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# TECHNOLOGY CASE STUDIES

## *Final Report*

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# 1.0 INTRODUCTION AND METHODS

## 1.1 Introduction

This volume was produced as part of the HCFA-funded research project entitled "Physician Reaction to Price Changes." In 1987 and 1988, substantial price reductions (mandated by OBRA-86 and OBRA-87) went into effect for twelve diagnostic and therapeutic surgical procedures. The practical question addressed by this project is whether physicians, as a response to these price cuts, reduced services to Medicare beneficiaries, or whether they performed even more procedures on Medicare patients in order to maintain target incomes. In a separate report, quantitative results will be presented from analyses of Medicare claims data from 1985 to 1989. For each procedure, the association between changes in utilization and the magnitude of price reductions will be determined, and inferences concerning physician response to price reductions will be made based on these associations.

Of course, non-price factors may also affect utilization rates of surgical procedures. In this volume, we explore some of these non-price factors for each of the twelve procedures whose reimbursement was reduced by OBRA-86 and OBRA-87. Our intent has been to produce for each procedure a "technology case study" which is accessible to health policymakers without clinical backgrounds. Therefore, each case study begins with an overview of relevant anatomy and disease processes, and is followed by a description of the surgical procedure, general indications, and possible complications. Finally, we analyze the technological changes which occurred in the 1980s which may have influenced utilization of these procedures during the 1985-1989 study period. These technological changes have been grouped into four categories:

- changes in technology which altered the risk/benefit ratio for a procedure;
- application of existing technologies to a broader range of clinical conditions (i.e., changes in clinical indications);

- shifts of procedures to ambulatory settings; and
- development of physician practice guidelines which fostered wider, or more limited, use of a technologically stable procedure.

## 1.2 Methods

For each of the twelve procedures, an on-line search was performed of the National Library of Medicine's bibliographic databases, using GRATEFUL MED software. Relevant references from the on-line search were obtained from the Countway (Harvard Medical School) Library, and were reviewed by our two staff physicians, Drs. Boutwell and Stason (an internist and cardiologist, respectively). In addition, the American Medical Association and medical specialty societies were contacted to obtain practice guidelines and policy statements relevant to the twelve procedures.

Our two physicians then prepared outlines from the published literature and from available guidelines, summarizing the important clinical and technological issues for each procedure. Consultants from appropriate medical and surgical specialties were selected based on suitable clinical experience, affiliation with teaching hospitals and medical schools, and demonstrated interest in health policy issues. The specialties represented included: cardiology, gastroenterology, obstetrics-gynecology, ophthalmology, orthopedic surgery, pulmonary medicine, and urology. We conducted extensive telephone interviews with our consultants to clarify the issues and questions identified through literature review. A technology case study was then written for each of the twelve procedures, based on the literature review and the telephone interviews. It is important to note that our consultants did not have an opportunity to review the written case studies. Their participation in this project should not, then, be taken as an endorsement of the final written form of the case studies. However, a list of consultants who participated in the interview stage of this process is included as Appendix A.

# 2.0 BRONCHOSCOPY

## 2.1 Relevant Anatomy and Pathology

The large airway below the larynx is the ***trachea***, a single passage stiffened by cartilage. The trachea divides into the right and left mainstem ***bronchi***. These two mainstem bronchi form a ***bronchial tree***, by branching first into several ***lobar bronchi***, then into ***segmental*** and ***subsegmental bronchi, terminal bronchioles, respiratory bronchioles***, and finally ***alveolar ducts***. The bronchial tree delivers inspired air to the sac-like functional units ***(alveoli)*** of the lung where gas exchange takes place between circulating blood and the external environment.

The bronchial tree, down to the level of the terminal bronchioles, contains several specialized components, including mucous-secreting cells, muscle cells, nerve endings, and hair-like projections called ***cilia***. Inhaled particles are trapped by mucous secretions, and the mucous is continuously swept upwards toward the throat by cilia. Chronic exposure to irritants such as smoke often increases mucous production, but damages or eliminates the cilia, thus decreasing the clearance of mucous from airways. Muscle cells in the bronchial tree cause bronchial constriction or bronchospasm in response to a number of stimuli, including mechanical or chemical irritants, infection, and inflammation. Nerve endings in the bronchial tree, in response to these same factors, can stimulate a cough reflex.

Some common disorders affecting the bronchial tree are inflammation and infection (acute bronchitis); bronchospasm (asthma); obstruction of airways by excessive mucous (chronic bronchitis, chronic obstructive pulmonary disease or COPD); and primary cancer arising in the bronchial lining. Some common disorders affecting the alveoli (the gas-exchanging units of the lung) are infections (pneumonia); inflammation (pneumonitis); and destruction of alveolar walls (emphysema). Cough, increased mucous production, and ***hemoptysis*** (coughing up blood) are non-specific symptoms that can be found with most of these disorders.

## 2.2 Indications for Bronchoscopy

Common indications for diagnostic bronchoscopy are to investigate chronic unexplained symptoms such as coughing or hemoptysis, to determine the cause of abnormal markings on chest X-ray, and to diagnose puzzling inflammatory and infectious conditions. Bronchoscopy has also been used therapeutically to retrieve small inhaled objects (a problem more frequently observed in small children than in adults), to remove thick mucous plugs not loosened by medications, and to assist occasionally in the placement of endotracheal tubes in patients requiring mechanical ventilation.

## 2.3 Description of Procedure

A fiberoptic bronchoscope is a long thin tube containing flexible glass fibers (fiber optics) and two or more channels used for instrumentation and suctioning. From an external source, light travels down the glass fibers to illuminate the area under examination. Reflected light travels up the glass fibers again, presenting an image to the examining physician.

During the procedure, the tip of the bronchoscope is introduced into the patient's nose or mouth, and passed through the throat and larynx into the trachea. The bronchial tree is a highly branched structure, and an extensive bronchoscopic examination requires advancing and withdrawing the instrument repeatedly to enter different parts of the bronchial tree. Abnormalities seen with the bronchoscope may be sampled in several ways: by "washing" the area with a small amount of liquid and suctioning the fluid back out ***(bronchial wash)***; by scraping the surface of the abnormal area with a wire-controlled brush ***(bronchial brush)***; by biopsying the bronchial lining or surrounding tissue using wire-controlled forceps ***(endobronchial*** or ***transbronchial biopsy)***; and by inserting a needle through the bronchial wall into lymph nodes or alveolar tissue ***(transbronchial needle aspiration)***. Tissue samples obtained through any of these methods are sent for pathological examination and may

also be cultured for bacteria and other pathogens. In some cases, fluoroscopy may be used to guide the biopsy forceps or needle to an abnormality identifiable on chest x-ray.

Bronchoscopy is performed with local anesthesia to reduce or eliminate gagging when the bronchoscope is passed through the throat. Many bronchoscopists (who are nearly always pulmonary specialists or thoracic surgeons) also use intravenous sedation to reduce anxiety; however, patients remain conscious throughout the procedure. Patients must fast for 12 hours before bronchoscopy to prevent vomiting and aspiration of gastric contents. Bronchoscopy is commonly performed as an ambulatory procedure, and most patients can be discharged to home within a few hours.

Decreased respiration and oxygenation ***(hypoxia)*** are the most common complications of bronchoscopy for several reasons: all patients have chronic or acute respiratory disease (such as bronchospasm or obstruction); ventilation is impaired somewhat by the presence of the bronchoscope in the bronchial tree; the bronchoscope itself can induce bronchospasm by mechanical irritation; and intravenous drugs given to reduce anxiety can reduce respiratory drive as well. Many patients also have cardiac disease, and cardiac arrhythmias during bronchoscopy are not uncommon. However, serious respiratory and cardiac complications can be minimized by monitoring of blood oxygen levels and cardiac rhythm.

Transbronchial biopsy and needle aspiration pose two additional risks: bleeding and ***pneumothorax*** (introduction of air into the chest cavity surrounding the lung). These complications are rarely life-threatening, but require additional observation and perhaps intervention.

## 2.4 Changes in Technology Affecting Risk/Benefit Ratio

One significant technological improvement has been a reduction in the diameter of bronchoscopes. Many pulmonary specialists are now regularly using bronchoscopes that are one-third smaller than those of five or ten years ago. These smaller scopes improve the risk-benefit ratio of bronchoscopy in several ways. They are less likely to cause hypoxia since they obstruct the airway

less. They can also be maneuvered further out in the bronchial tree, to the level of subsegmental bronchi, increasing the number of abnormalities that can be examined bronchoscopically. Finally, smaller scopes are somewhat better tolerated by patients since the sensation of pressure in the throat is less.

For those patients who do receive intravenous sedation for bronchoscopy, the introduction of Versed in 1986 offered some advantages. The drug takes effect very quickly but has a shorter half-life than Valium, the drug it replaced. Patients therefore recover from sedation more rapidly. Moreover, administration of Versed usually causes a brief period of amnesia without loss of consciousness; most patients who receive Versed will remember little or nothing of the procedure. An important disadvantage of Versed, however, is that it may cause decreased respiration more frequently, especially when used in doses equivalent to that of Valium. Greater experience with Versed, and downward adjustment of doses, have reduced this risk.

The risk-benefit ratio has also been improved by the use of videoscopes, a technology that was diffusing in the late 1980s. Images can now be viewed on video screens, rather than through small telescope-like lenses. The larger image improves diagnostic accuracy. Clinical teaching is more effective, since all participants view the same image simultaneously. Quality of care may also improve, since diagnostic findings and therapeutic maneuvers can be videotaped and reviewed later. The advantages of videoscope technology, however, may be limited largely to teaching hospitals due to its high cost.

The benefits of bronchoscopy have also recently expanded to include therapy as well as diagnosis of bronchogenic cancer. In ***brachytherapy***, a radioactive wire is inserted in the bronchus via bronchoscopy and left in place for several hours; the procedure can be used in place of, or as an adjunct to, external radiation therapy to shrink an obstructing tumor. Bronchoscopic laser therapy has also been available clinically for about five years to reduce the bulk of bronchial tumors. Both of these bronchoscopic treatments are palliative rather than curative.

## 2.5 Changes in Indications for Bronchoscopy

The availability of bronchoscopic therapies such as brachytherapy and laser ablation of tumors has had relatively little impact on overall utilization rates. Most bronchoscopy is performed for diagnostic purposes.

The use of smaller-diameter bronchoscopes has meant that patients with abnormalities located more peripherally in the bronchial tree can now benefit from diagnostic bronchoscopy. Increased use of transplantation, and consequently of immunosuppressive therapy, has also increased the pool of individuals requiring bronchoscopy: many of these patients will undergo repeated procedures to look for evidence of inflammatory reactions in the lung that accompany organ rejection, or to diagnose opportunistic pulmonary infections associated with immunosuppression. (Patients with AIDS are also likely to undergo diagnostic bronchoscopy; however, few AIDS patients are covered by Medicare.)

Bronchoscopy has found another application in intensive care patients on mechanical ventilators. Ventilators deliver air to the lungs through endotracheal tubes, which are inserted through the mouth into the trachea. A cuff at the bottom of the tube is inflated against the tracheal wall, so that air can be forced into the lungs through the tube without leaking. It is critical that the end of the tube be properly positioned in the trachea below the larynx and not in the right or left main-stem bronchus, so that both lungs are ventilated. A radio-opaque stripe runs down the length of all endotracheal tubes, so that their position can be checked by chest X-ray after placement. Bronchoscopy occasionally must be used to place such tubes properly. However, the procedure is being used increasingly in intensive care units to check the position of endotracheal tubes immediately after routine (non-bronchoscopic) placement, rather than wait until a portable X-ray machine can be brought to the intensive care unit. In some cases, both bronchoscopy and chest X-rays are used to determine the position of the tube; either procedure is sufficient, and chest X-ray is usually less expensive.

## 2.6 Shifts of Bronchoscopy to Ambulatory Settings

Since 1985, the usual location of bronchoscopy has shifted from inpatient to ambulatory settings. Most procedures are now done in ambulatory surgical units located within hospitals, where patients can be observed for several hours following the procedure. No significant technical breakthroughs were necessary for this shift; rather, it is more likely attributable to increased pressure from payors, and to increased experience and confidence of physicians in their ability to recognize complications. Today, the only patients likely to be admitted for bronchoscopy are those at increased risk from medical conditions such as recent myocardial infarction; unstable cardiac arrhythmias; and marginal lung function with increased risk for respiratory failure (especially if intravenous sedation is used). Patients who experience complications during bronchoscopy (such as significant hemoptysis or pneumothorax) are also admitted.

## 2.7 Development of Clinical Guidelines

In 1986, the American Thoracic Society (ATS) published its "Guidelines for Fiberoptic Bronchoscopy in Adults." The guidelines are concise and enumerate both diagnostic and therapeutic indications for bronchoscopy. They also list a number of conditions in which hospital admission for bronchoscopy may be necessary. The guidelines reflected the common practice of well-trained pulmonary specialists, and were not controversial.

However, more detailed statements would have been helpful regarding the appropriateness of diagnostic bronchoscopy in several clinical conditions. For example, the procedure is frequently used to establish or exclude the diagnosis of cancer when the patient's chest X-ray shows new suspicious abnormal densities. Even when the chest X-ray abnormalities are entirely consistent with pneumonia or atelectasis (localized collapse of lung tissue), the possibility remains (although usually remote) that an unseen tumor is contributing to the pneumonia or atelectasis by obstructing a bronchus, preventing inflation and drainage of lung tissue beyond the obstruction.

Since pneumonia and atelectasis are common conditions in the elderly (atelectasis frequently occurs following surgery), most pulmonary specialists will not routinely perform bronchoscopy for these conditions, but will reserve bronchoscopy for those cases in which X-ray abnormalities do not resolve within the expected period of time. The authors of an editorial in the journal Chest stated in 1989 that they "avoid FFB [flexible fiberoptic bronchoscopy] for at least six to eight weeks for slowly resolving pneumonia (radiographically) in a patient who is clinically recovering." Other physicians are more aggressive in bronchoscoping patients whose chest X-rays are consistent with pneumonia or atelectasis, out of fear of missing a diagnosis of cancer. However, low thresholds for invasive procedures in patients with pneumonia and atelectasis may contribute significantly to overutilization of bronchoscopy. More specific guidelines from the ATS regarding use of bronchoscopy in pneumonia and atelectasis would have been helpful.

Two other conditions in which more explicit guidelines would be helpful are unexplained cough and hemoptysis. A chronic cough is an annoying and potentially worrisome symptom. However, the coughing reflex can be stimulated by a number of conditions besides cancer, including: allergic rhinitis ("hay fever") with postnasal drip; asthma; heart failure; and irritation from cigarette smoke. In one study (Poe et al.) of 51 patients with chronic persistent cough and a normal chest X-ray, only one patient was found to have cancer on bronchoscopy. These authors concluded that "bronchoscopy is of limited value in determining the cause of isolated chronic cough." Another condition in which the use of bronchoscopy is controversial is in the evaluation of hemoptysis. The severity of hemoptysis ranges from coughing up small amounts of blood-tinged mucous to large amounts of frank blood. Common causes of hemoptysis include bronchitis and lung cancer. However, the incidence of lung cancer in patients with normal chest-rays is reported by some studies to be less than 5 percent. The 1986 ATS guidelines on bronchoscopy do state that "bronchoscopy is not a routine initial procedure in the evaluation of unexplained cough," but provide no further clarification of the role of the procedure in evaluating unexplained cough or hemoptysis. When

patients are referred by primary care physicians for these symptoms, pulmonary specialists may feel pressured to perform bronchoscopy as a definitive diagnostic procedure to avoid loss of referrals, even if other evidence (e.g., medical history and chest X-ray) make serious disease such as cancer unlikely.

## 2.8 Summary

Although it has some limited therapeutic applications, bronchoscopy is used primarily to diagnose inflammatory, infectious, and malignant diseases of the bronchial tree and lung. Utilization of diagnostic bronchoscopy undoubtedly increased following the development of smaller-diameter scopes which could reach more peripheral lesions. Increased use of immunosuppressive therapy for organ transplantation has also increased the number of patients in whom bronchoscopy is indicated.

It is likely that the effects of technology changes on utilization of bronchoscopy are equalled or exceeded by the impact of changes in physician practice patterns, particularly regarding use of bronchoscopy in uncomplicated pneumonia and atelectasis. However, no broad-based studies of the appropriateness of bronchoscopy in the United States have been published, and estimates of overutilization or underutilization are not available. Guidelines published by the American Thoracic Society in 1986 are unlikely to have had a significant effect on curbing possible overutilization.

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# 3.0 CARPAL TUNNEL RELEASE

## 3.1 Relevant Anatomy and Pathology

The ***median nerve*** begins at the shoulder and travels down the arm and wrist to the base of the thumb, where it enters the hand. It is both a sensory nerve and a motor nerve. As a sensory nerve, it carries information to the brain from the thumb, index finger, middle finger, and half of the ring finger. As a motor nerve, it provides stimulation to muscles which flex the fingers and rotate the thumb and wrist.

As the median nerve crosses from the wrist into the hand, it passes through the ***carpal tunnel***, a canal formed by the ***carpal bones*** (small bones in the back of the hand) and the ***transverse carpal ligament*** (the very hard structure at the base of the palm, just above the wrist). The median nerve may become compressed or entrapped as it passes through the carpal tunnel. Causes of such median nerve entrapment include: conditions which cause a decrease in the size of the carpal tunnel (e.g., rheumatoid arthritis affecting the wrist; immobilization of the wrist in a flexed position during treatment for wrist fracture); enlargement of the median nerve (from systemic diseases such as diabetes or hypothyroidism, or from abnormal growth of nerve tissue); and other conditions which increase pressure on the median nerve in the carpal tunnel (e.g., inflammation of tendons; crystalline deposits from gout; fluid retention in pregnancy). Probably the most common causes of median nerve entrapment, however, are occupational or avocational activities involving frequent pressure on the base of the palm (lifting weights, using screwdrivers and other hand tools), or repetitive movements of the wrist and fingers (typing, knitting, crocheting, playing musical instruments). The condition may be unilateral (typically affecting the dominant hand in occupationally-related cases) or bilateral (more likely to occur with systemic conditions such as rheumatoid arthritis, diabetes, hypothyroidism, and pregnancy).

When median nerve entrapment becomes symptomatic, it is called ***carpal tunnel syndrome***. The syndrome is very common, occurring usually after age 30 and more frequently in women than in men. The first symptoms are related to the sensory function of the median nerve. These typically include numbness and tingling in the fingertips, occurring at night and sometimes interfering with sleep. As symptoms progress, numbness and tingling become more frequent, and the patient may experience burning pain in the fingers and hand, extending sometimes down the forearm. The patient may also have symptoms related to the motor function of the median nerve, and notice a weakened grip or clumsiness in performing tasks with the fingers such as unscrewing bottle caps. Symptoms related to mild or moderate carpal tunnel syndrome are reversible if treatment is obtained in a timely manner. In advanced cases, however, irreversible damage to the motor and sensory portions of the median nerve may occur.

On physical examination, patients with carpal tunnel syndrome usually have decreased sensation to pinprick over the first three fingers and show some weakness in certain movements of the thumb. The prominent muscle in the palm, at the base of the thumb, may be noticeably shrunken ***(thenar wasting)***; such wasting is evidence of more advanced median nerve compression. The diagnosis of carpal tunnel syndrome may be confirmed by nerve conduction studies, which can detect abnormal slowing of sensory and motor impulses in the fingers and hand. (Pressure within the carpal tunnel may be measured directly by inserting a special catheter into the wrist and advancing it into the carpal tunnel; however, this technique is used far more in research than in clinical practice.) X-rays of the wrist may also be obtained to rule out arthritic changes or abnormal masses, and appropriate blood tests will be obtained if systemic disease is suspected.

## 3.2 Indications for Carpal Tunnel Release

Treatment for carpal tunnel syndrome depends upon the severity of symptoms and objective evidence of median nerve compression. For mild cases, conservative treatment is often prescribed. This includes cessation of activities which may increase pressure within the carpal tunnel (such as

typing, working with hand tools, and so forth), and use of an immobilizing wrist splint while at rest and at night, to maintain the wrist in a neutral position and relieve pressure within the tunnel. Many patients with mild symptoms will obtain complete relief from these conservative measures. Oral anti-inflammatory drugs or injection of corticosteroids into the carpal tunnel may also be tried.

For patients with advanced symptoms or with thenar wasting, and for patients who have not been helped by conservative measures, surgery is indicated.

## 3.3 Description of Procedure

Carpal tunnel release may be performed by any surgeon who specializes in hand surgery. Such surgeons are usually orthopedic specialists, neurosurgeons, or plastic surgeons. A midline incision is made from the wrist to the middle of the palm, exposing the transverse carpal ligament. A small section of this ligament is cut to reveal the median nerve within the carpal tunnel. After the median nerve has been identified and tagged to prevent inadvertent injury, the transverse carpal ligament is cut completely in two, releasing pressure in the carpal tunnel. This, in essence, is a carpal tunnel release. (The transverse carpal ligament has little anatomic function other than to protect the carpal tunnel. When it is cut in two, a gap of only one to two centimeters is created, and this gap eventually is closed by fibrous bands.)

For patients with severe or long-standing carpal tunnel syndrome, an additional procedure called ***neurolysis*** may be performed. After the transverse carpal ligament is cut, the median nerve may be dissected away from surrounding tissues (such as fibrous bands or adhesions) to further reduce nerve compression. The benefits of neurolysis have been disputed, however.

When carpal tunnel syndrome is related to rheumatoid arthritis, an additional procedure is often performed with carpal tunnel release. One of the principal pathological processes in rheumatoid arthritis is an inflammatory reaction in the membrane ***(synovium)*** which surrounds the tendons

which flex the fingers. The synovium becomes thickened and irregular. When rheumatoid arthritis affects the wrist, this synovial thickening around the flexor tendons at the wrist can impinge on the carpal tunnel, causing median nerve entrapment. In such cases, a ***tenosynovectomy*** is performed to remove the diseased flexor tendon synovium and prevent recurrence of carpal tunnel syndrome.

Carpal tunnel release is usually performed as an ambulatory procedure under local or regional anesthesia. Patients at increased surgical risk and patients undergoing bilateral release may require admission. Following surgery, the hand and wrist are bandaged, and the patient wears a splint for three weeks to maintain the wrist in a neutral position. Most patients achieve good relief of symptoms following surgery, and can return to their former level of activity (including repetitive hand and wrist motions) within two to three months.

Complications of carpal tunnel release include severance of branches of the median nerve, cosmetically unacceptable scars on the wrist and palm, and formation of adhesions between tendons in the hand. These complications can usually be avoided by good surgical technique.

## 3.4 Changes in Technology Affecting Risk/Benefit Ratio

Carpal tunnel release was a technologically stable procedure throughout most of the 1980s. However, in the late 1980s, an endoscopic technique of carpal tunnel release was developed in Japan. An endoscope is inserted through the skin near the wrist, and advanced to a position below the transverse carpal ligament. The ligament is then cut endoscopically. Unlike the wrist-to-palm incision used in the standard procedure, endoscopic release leaves a much smaller surgical wound and scar, reducing recuperation time, and making it easier for patients to care for themselves postoperatively since no bulky dressing is required. Disadvantages of the procedure is that it is technically more difficult for the surgeon, requiring more skill to avoid

inadvertent severing of median nerve branches. Furthermore, the endoscopic procedure cannot be used in patients with rheumatoid arthritis who require synovectomies at the time of carpal tunnel release.

Endoscopic carpal tunnel release is likely to grow in popularity in the U.S. for several reasons. Because of decreased post-surgical disability and recuperation, patients are likely to prefer the technique. Surgeons may feel compelled to learn the technique to remain competitive. Increased availability of endoscopic release may make surgery a more acceptable alternative to patients with less severe symptoms, and thus increase utilization of carpal tunnel release. However, endoscopic carpal tunnel release was being used experimentally in only a few centers in the U.S. in the late 1980s, and still has very limited use in this country. It would not have had any noticeable effect on utilization of carpal tunnel release during the 1985 to 1989 study period.

### 3.5 Changes in Indications for Carpal Tunnel Release

Carpal tunnel release is performed on patients with a specific and rather narrow complex of symptoms and findings on physical exam (carpal tunnel syndrome). The definition of the syndrome is stable (i.e., is not undergoing revision or expansion with changes in medical knowledge). It is possible that the threshold for considering surgery is changing, so that patients with less severe symptoms are more likely to undergo carpal tunnel release. This might happen, for example, if patients become more knowledgeable about carpal tunnel syndrome and are therefore more likely to seek medical care for minor symptoms and to request surgery. Changes in the threshold for surgery might also occur if physicians become more aggressive about surgical intervention in less severe cases, in order to avoid permanent nerve damage. However, there is no literature which documents such changes in the threshold for this procedure.

## 3.6 Shifts of Carpal Tunnel Release to Ambulatory Settings

Use of local or regional anesthesia in carpal tunnel release has been standard for a number of years, and most such procedures were being performed in ambulatory settings by 1985.

## 3.7 Development of Clinical Guidelines

The American Academy of Orthopaedic Surgeons has developed a set of "clinical policies" for six orthopedic conditions, including carpal tunnel syndrome. Since these were published for the first time in January 1990, they could not have had any effect on utilization of carpal tunnel release between 1985 and 1989. The clinical policies list diagnostic and therapeutic options, but provide little discussion of the appropriateness of these options in various clinical settings. Even had these guidelines been available earlier, it is unlikely that they would have had a large impact on utilization.

## 3.8 Summary

Carpal tunnel syndrome is a specific and fairly common cluster of symtoms and signs related to compression of the median nerve at the wrist. Diagnosis of the syndrome is usually made on the basis of symtoms and physical examination, but can be confirmed by nerve conduction studies and by directly measuring pressure within the carpal tunnel.

Endoscopic carpal tunnel release may become common in the U.S. within the next few years; however, its use here has been extremely limited to date. The standard carpal tunnel release procedure has been technologically stable for years, as has the risk/benefit ratio associated with the procedure. It is possible, however, that some increase in utilization might be attributable to increased patient awareness of carpal tunnel syndrom and its surgical treatment, and to a shift in physician preference to earlier surgical treatment of compression to minimize the risk of permanent nerve damage.

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# 4.0 CATARACT EXTRACTION

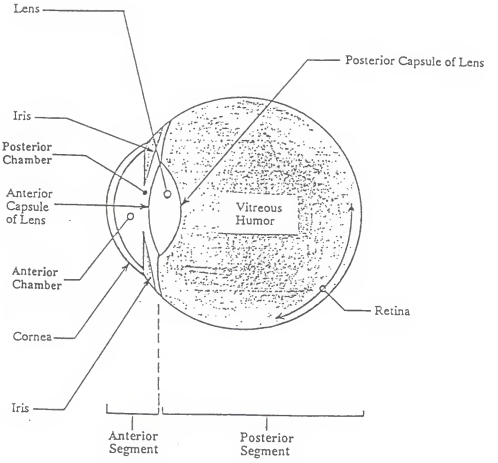
## 4.1 Relevant Anatomy and Pathology

The ***lens*** of the eye is composed of transparent fibers. New fibers are formed at the periphery of the lens, and older fibers are crowded together at the center, becoming more densely packed with age. Eventually, the lens begins to opacify, particularly at its center; these lens opacities are called ***cataracts***. In this sense, cataracts are a normal part of aging, although the extent of opacification and the age at which it becomes symptomatic vary across individuals. The process is nearly always bilateral: both eyes are affected, but again often at different rates.

Lens opacities associated with aging are called ***senescent*** or ***senile*** cataracts, and constitute the vast majority of all cataracts. Opacification of the lens can also be caused by trauma to the eye, infection, microwaves and other forms of radiation, systemic illnesses such as diabetes mellitus, and drug therapy (particularly corticosteroids). ***Congenital*** cataracts (present at birth) are associated with genetic disorders such as Downs' syndrome, intra-uterine infections such as rubella, and other factors.

The lens is surrounded by a clear membrane called the ***lens capsule*** (Fig. 4-1), which holds the lens in place. Immediately anterior to the lens is the ***iris***, a circular pigmented muscle which functions like the diaphragm in a camera to adjust the amount of light admitted to the eye.

Most of the globe of the eye (the ***posterior segment***) is filled with a transparent jelly-like material called the ***vitreous humor***. However, a small portion at the front of the eye (the ***anterior segment***) contains a clear liquid called the ***aqueous***. The iris divides this anterior segment of the eye into two parts. The ***anterior chamber*** is the space between the cornea and the iris. The ***posterior chamber*** is the space between the iris and the posterior capsule of the lens.




Schematic Diagram of Eye

Figure 4-1

## 4.2 Indications for Cataract Surgery

Nearly everyone over the age of 60 has some opacification of the lens. However, not all cataracts impair vision; those that do are called symptomatic cataracts. By age 75, over half the population will have diminished visual acuity attributable to cataracts. The first symptom is usually difficulty seeing clearly in bright light because of glare. Objects may seem to have halos, since the central lens opacity causes light to diffuse. Vision is better in dim light or at night: under these conditions, the iris is open wider, exposing more of the peripheral (and less opacified) lens. With a far advanced cataract (i.e., nearly totally opacified lens), the affected eye is functionally blind.

Cataracts do not need to be removed unless they significantly impair vision. When this occurs, however, the only treatment is surgery to remove the opacified lens. Cataracts are progressive and do not respond to medications. Since lens opacities are present in most individuals by age 60, but not all are symptomatic, cataract surgery is indicated only when:

- significant visual symptoms or impairment of visual acuity has been documented, and
- it is apparent that the visual symptoms or loss of acuity is caused by cataract, rather than by poor refraction, retinal disease, or other problems.

## 4.3 Description of Procedure

Cataract surgery is nearly always performed under local anesthesia with intravenous sedation and analgesia. Local anesthetic agents are injected around and behind the eye, paralyzing the eye and eyelid, and eliminating sensation in the area. The patient remains awake throughout the procedure. Because of its greater risks, general anesthesia is reserved for children with congenital cataracts and for extremely anxious patients.

Several methods have been developed to remove the lens from the eye. The most widely used technique until the 1980s was ***intra-capsular cataract extraction*** (ICCE). In this method, the lens is removed along with its

capsule. First, a long incision is made at the edge of the cornea. The cornea is lifted, exposing the iris and the lens behind it. The lens and its capsule are removed using forceps, suction, or other devices. After an ICCE, the iris is the only structure remaining in the anterior segment of the eye that is capable of supporting an implanted artificial lens.

In the 1980s, ***extra-capsular cataract extraction*** (ECCE) began to replace intra-capsular extraction (ICCE) in the United States. With extra-capsular extraction, the cornea is lifted to expose the iris and lens, but instead of removing the entire lens capsule, only the anterior capsule (the membrane covering the anterior surface of the lens) is excised. The lens itself is then removed, leaving the posterior capsule in place. After an ECCE, an artificial intra-ocular lens can be positioned between two stabilizing structures: the iris and the posterior capsule of the surgically-removed lens.

Other methods for cataract extraction have been developed. In ***phacoemulsification***, the anterior capsule is removed and the lens is fragmented by ultrasound. The fragments are then aspirated, leaving the posterior capsule in place (as with ECCE). However, phacoemulsification is often unsatisfactory in elderly patients, whose lenses are denser and do not emulsify easily with ultrasound. The high cost of phacoemulsification equipment has also limited diffusion of the technique.

There are many potential complications of cataract extraction, including inflammation, infection, hemorrhage, retinal detachment, and glaucoma. Inflammation and retinal detachment may be more common with intra-capsular extraction. When the posterior capsule of the lens is removed, it exerts traction on the vitreous humor. Inflammation can result if bits of the vitreous are pulled into the anterior segment of the eye. Since the vitreous is also attached to the retina, changes in the vitreous that occur during or after ICCE can also cause the retina to detach from the posterior wall of the eye.

However, ECCE is associated with a problem never seen following ICCE. The posterior lens capsule (which is not removed during ECCE) often becomes cloudy and interferes with vision. In such cases, the posterior capsule is referred to as a ***secondary, membranous***, or ***after cataract***. Such cataracts

occur in perhaps 40 percent of patients within two years of cataract extraction. These opacified lens capsules can be treated by again opening the eye at the cornea, removing any artificial intra-ocular lens, and cutting the posterior capsule (a procedure known as ***discission of secondary membranous cataract*** in CPT-4 terminology). However, a newer technique uses a neodymium-YAG (yttrium-aluminum-garnet) laser to rupture the opacified posterior capsule without opening the eye at all. Laser treatment of secondary cataracts is an office procedure, and can be performed with intra-ocular lenses in place. YAG laser treatment has become the preferred therapy for secondary membranous cataracts, which are increasing in incidence because of the growing use of extra-capsular cataract extraction.

## 4.4 Changes in Technology Affecting Risk/Benefit Ratio

The diffusion of the operating microscope and microsurgical techniques in the late 1970s and early 1980s made cataract surgery safer and more dependable. Before this time, ophthalmologists relied on loupes (magnifying glasses mounted on a headband or eyeglass frames) during cataract surgery. The operating microscope allows for more precise control of incisions and other surgical maneuvers, and permits the surgeon to place extremely fine sutures with great accuracy. Surgical wounds became substantially smaller, lowering the risk of infection and other surgical complications, and eliminating the need for total immobilization of the patient following cataract surgery. Diffusion of microsurgical techniques was probably nearly complete by 1985.

The most important technological changes affecting utilization of cataract surgery were improvements in artificial intra-ocular lenses (IOLs) that began about 1975 and are continuing today. Following cataract surgery, uncorrected vision is very poor, since there is no longer a lens to focus light upon the retina. Before the widespread availability of intra-ocular lenses, vision in the post-cataract patient could be corrected using either glasses or contact lenses (applied externally to the cornea). Contact lenses require considerable manual dexterity to insert and remove, and are very

difficult to use for most elderly post-cataract patients. Thick spectacles, the alternative to contact lenses, were easier for patients to find and put on. However, these glasses magnify images by up to 30 percent, distort peripheral vision, and alter spatial perception. Since patients cannot resolve the distorted vision from one eye with the perspective of a normal eye, such glasses are suitable only for those who have had cataract extractions in both eyes. Even so, many patients with bilateral cataract extractions are unsatisfied with the distorted vision provided by these glasses. Problems with existing methods of visual correction limited the benefits of cataract extraction for patients with mild or moderately symptomatic cataracts: surgery could mean trading one form of visual impairment for another.

Intra-ocular lenses are implanted permanently in the eye, in either the anterior or the posterior chamber (that is, in front of or behind the iris). They may be implanted immediately following cataract extraction or at any time thereafter. Intra-ocular lenses were first implanted in humans in 1949. Early lenses frequently caused complications such as inflammation of the eye and glaucoma, and often needed to be removed. When placed in the anterior chamber, between the iris and the cornea, the artificial lens frequently caused mechanical abrasion of the cornea. When placed in the posterior chamber, between the iris and the posterior capsule, the heavy lenses often became dislocated. In the 1950s, newer lenses were developed which clipped onto the iris itself. However, these lenses also caused inflammation and glaucoma, and in addition caused shrinking or wasting of the iris. Because of various technical problems involving both surgical techniques and the design and manufacture of the lenses, IOLs were considered experimental and were not widely used throughout the 1950s and 1960s.

Since 1975, great improvements have been made in the design and manufacture of intra-ocular lenses and in the techniques by which they are implanted in the eye. In place of the anterior chamber and iris-fixated lenses used previously, nearly all modern IOLs are inserted into the posterior chamber, where they are supported by the posterior capsule. Inflammation, glaucoma, and other complications are less likely when the posterior capsule

is left intact and used to support the IOL, largely because the vitreous humor is not disturbed and because mechanical irritation between the IOL and the iris or cornea does not occur. Posterior-chamber IOLs require the use of extra-capsular cataract extractions, accounting for the rapid shift to this form of cataract surgery. Use of the operating microscope and microsurgical techniques allow surgeons to completely remove remnants of lens tissue from the posterior capsule; such remnants were often responsible for inflammatory reactions when extra-capsular extraction was performed before development of the operating microscope. These microsurgical innovations have also improved surgeons' ability to position and support IOLs properly within the posterior chamber. Furthermore, ultrasound techniques allow precise intra-ocular measurements and estimation of the optical strength required of each IOL before it is implanted. Lastly, manufacturing processes have been improved to produce more highly polished IOLs with less residue from polishing agents and sterilizing solutions and gases. These cleaner, smoother lenses are less likely to cause irritation and inflammation.

The result of all of these changes in intra-ocular lens technology was to increase the benefits of cataract extraction for patients with moderate or even mild visual symptoms, since the newer IOLs provided nearly normal vision with little inconvenience and a very low incidence of complications. Today, the vast majority of patients undergoing cataract extraction receive IOLs during the same operating room session. Although improvements in IOL technology are continuing (such as the development of soft IOLs, which can be rolled tightly and implanted through a much smaller incision), most of the technical improvements described above took place between the mid-1970s and mid-1980s. A very noticeable result of these improvements was a substantial increase in the utilization of cataract surgery throughout the 1980s.

## 4.5 Changes in Indications for Cataract Extraction

The general indications for cataract extraction have not changed: visual symptoms or loss of visual acuity must be documented; and the symptoms or decreased vision must be attributable to cataracts. However, the threshold

for performing surgery has decreased markedly as a result of improvements in surgical techniques and especially in IOL technology. Surgery is now considered for patients with vision better than 20/40 in the affected eye, if their subjective complaints of symptoms (such as disabling glare in bright light) can be documented.

It should also be noted that the number of persons requiring cataract surgery is increasing as the population ages. However, the effect of population aging on utilization of cataract surgery will be small over the span of a few years; most of the the increase in utilization is attributable to improvements in technology which have altered the risk/benefit ratio of the procedure, and made it a satisfactory form of treatment for a larger pool of individuals.

## 4.6 Shifts of Cataract Surgery to Ambulatory Settings

The development of microsurgical techniques in the late 1970s markedly reduced the size of surgical wounds from cataract extraction, and thus lowered the risk of wound complications (such as infection and leakage of fluid from the eye). It was no longer necessary to completely immobilize the patient or to apply constant pressure to the surgical wound. Diffusion of microsurgical techniques in the late 1970s and early 1980s made it possible to perform cataract surgery routinely as an ambulatory procedure. However, HCFA policy mandates in the early 1980s required nearly all cataract procedures to be performed in ambulatory settings.

## 4.7 Development of Clinical Guidelines

In 1989, the American Academy of Ophthalmology (AAO) published its first set of guidelines on cataract surgery, called Cataract in the Otherwise Healthy Adult Eye. The guidelines acknowledge the impact of changes in surgical techniques and IOL technology on cataract surgery utilization, and

state that "extracapsular cataract extraction...with implantation of a posterior chamber IOL is the current procedure of choice in the vast majority of operations for removing uncomplicated cataracts."

The guidelines discuss indications for cataract surgery in only broad terms. According to the AAO, cataract surgery is indicated if "the best correctable visual acuity in the affected eye is 20/50 or worse" and if "the eye examination confirms that cataract is the limiting factor for improving visual function." However, even when vision in the affected eye is 20/40 or better, surgery may be indicated if warranted by the patient's subjective complaints (such as disabling glare, or problems with daily activities such as driving, reading, or watching TV). Such guidelines provide a great deal of latitude for physicians and patients in deciding whether cataract surgery should be done, and make it difficult to judge when surgery is used inappropriately.

Implicitly, however, the guidelines recognize by these general statements that no good objective criteria exist for determining when cataracts require surgery. Results of the Snellen visual acuity test (in which normal vision is 20/20) are highly dependent on the lighting levels under which the test is performed. Patients with cataracts may have nearly normal vision in a darkened room, but perform much worse under bright lights. They may notice their visual symptoms are more pronounced when driving towards the sun, or driving at night facing oncoming headlights. The guidelines recognize that visual acuity is not a sufficient standard for determining the appropriateness of cataract surgery, but that the true criterion is the degree of visual disability. Other objective methods of (such as glare testing) are now being explored as adjuncts to visual acuity as criteria for determining the appropriateness of cataract extraction. However, these methods have not been sufficiently standardized to be of clinical value in making decisions regarding surgery.

## 4.8 Summary

The rapid growth in the utilization of cataract surgery is attributable primarily to technological advances in surgical techniques and in the design and manufacture of intra-ocular lenses. The surgical procedure is safe and has reliably good outcomes, and post-cataract patients have nearly normal vision after IOL insertion. The decreased risks and increased benefits of combined cataract extraction and IOL insertion have made these procedures an acceptable treatment for a larger number of cataract patients with less severe visual symptoms.

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# 5.0 CORONARY ARTERY BYPASS GRAFT SURGERY

## 5.1 Overview

The treatment of coronary artery disease has undergone a dramatic evolution during the past 20 years. The first major advance was the development of coronary artery bypass graft (CABG) surgery in the late 1960s. CABG surgery became the mainstay of treatment for severe symptomatic coronary artery disease during the 1970s and into the 1980s when the introduction of balloon dilatation of coronary artery obstruction by percutaneous transluminal coronary angioplasty (PTCA) offered a viable alternative in selected patients. Present and projected future utilization patterns reflect both the unique contributions of each of these technologies and the competition between them. Improvements in medications to treat angina pectoris, dissolve or prevent blood clots in coronary arteries, and to slow the progression of coronary artery disease have further altered indications for invasive treatments and improved overall prognosis.

## 5.2 Relevant Anatomy and Pathology

The heart is a muscular pump that is remarkably well designed to supply the demands of other organs for oxygen and other blood-carried nutrients by altering its output in response to the highly variable demands imposed by physical exertion and other environmental factors. To meet these demands, the heart muscle, in turn, requires its own blood supply which is delivered in large measure through a branching system of coronary arteries.

A brief description of the anatomy of the coronary arteries will help the reader to interpret indications for CABG that are based on the number, locations, and severity of coronary artery obstructions as well as symptoms. There are two main coronary arteries, the left main coronary artery (LMCA) which supplies blood to the left ventricular muscle and the right coronary artery (RCA) which supplies the right ventricular muscle. Each main artery divides into a number of branches and, in fact, the left and right coronary

artery systems usually connect with each other in their ***distal*** branches (those furthest from the origin). The left coronary artery is in many ways the more critical because of the greater muscle mass of the left ventricle required to pump blood into the higher pressure systemic circuit that supplies most of the body. The right ventricle pumps into the lower pressure pulmonary artery circuit. The left main coronary artery (LMCA) branches into two major divisions, the left anterior descending (LAD) and the left circumflex (CX) artery each of which has a variety of ***proximal*** (those closest to the origin) and distal branches. Coronary artery disease may lead to narrowing or complete occlusion of any one or more of the main coronary arteries or their branches.

The number, locations, anatomical characteristics, and severity of coronary artery stenoses have important implications for the choice of CABG, PTCA, or medical treatment and for short- and longer-term prognosis. Critical coronary artery disease is traditionally classified as left main, one, two, or three vessel disease based on the presence of 70 percent or more reduction in the diameter of the LMCA or one or more of the RCA, LAD, and CX. Because of the extraordinary risk associated with occlusion of the LMCA, 50 percent obstruction is often accepted as evidence of "critical stenosis" for this vessel. The type and location of obstruction in any given coronary artery are also important considerations. Proximal and localized obstruction are well suited for either PTCA or CABG, while distal or diffuse obstruction are generally better treated by CABG.

## 5.3 Indications for CABG Surgery

Most candidates for CABG either have symptoms of angina pectoris which cannot be adequately controlled with medications or have had a myocardial infarction with residual patterns of myocardial ischemia that indicate they are at high risk of future infarctions. Less commonly, syncope or cardiac arrest may be the presenting symptom, and, occasionally, a coronary angiogram done in an asymptomatic patient will identify LMCA or extensive three vessel disease that suggests the need for CABG even in the absence of symptoms.

The treatment decision takes into account the type and severity of symptoms, anatomical findings on coronary angiography, and factors affecting the risk of the procedure such as the presence of left ventricular failure or significant comorbidities. The resulting benefit and risk assessments are complex ones. Available evidence indicates that CABG may extend life in patients with LMCA or three vessel disease and, possibly, in two vessel disease if the LAD artery is involved. Otherwise, the benefit from either CABG or PTCA is usually measured only in terms of improved quality of life due to better relief of symptoms than can achieved with medical therapy alone.

## 5.4 Description of Procedure

A CABG operation is an open heart procedure performed using a cardiopulmonary bypass machine. After the chest has been opened, the heart is isolated and the cardiopulmonary bypass machine is connected in a fashion that permits it to perform the functions of the heart and lungs while the coronary artery occlusions are being bypassed. The advantages of this technique are that the heart can be stopped and cooled during the procedure. Respectively, these steps permit the surgeon to have a still heart to operate on and protect the heart muscle from metabolic damage.

Bypasses of coronary artery occlusions are performed using either saphenous vein grafts obtained from the legs, internal mammary (internal thoracic) arteries obtained from the undersurface of the chest wall, or gastroepiploic arteries obtained from the region of the stomach. Venous grafts have the advantages of being more adaptable to being inserted wherever needed. Arterial grafts, while less mobile, have the distinct advantage of exhibiting better long-term graft patency. In either case, the vessels are small and microsurgerical techniques are required to join the grafts to coronary arteries.

Other procedures that may be performed during a CABG operation include ***left ventricular aneurysmectomy*** (excision of a non-functional region of myocardium), ***coronary*** or ***carotid endarterectomy***, or ***intraoperative coronary angioplasty***.

Complications

Complications of CABG surgery can be broadly divided into those occurring in the intraoperative and post-operative periods. Intraoperative complications include adverse reactions to anesthetic agents, technical surgical problems, and complications related to the cardiopulmonary bypass machine. A particularly critical time is when the operation has been completed and attempts are made to restart the heart and "wean" the patient off cardiopulmonary bypass. Problems are especially likely to be encountered in patients with pre-operative heart failure. In such cases, the first steps are to ensure that blood volume has been fully restored and to stimulate the heart muscle with medications. If these measures fail, an ***intraaortic balloon pump*** or ***ventricular assist device*** may be inserted to substitute for heart function and tide the patient over until the heart recovers sufficiently to function on its own. Post-operative complications increase the risk of operative mortality and also increase short- and long-term morbidity. The more common of these are bypass occlusion or bleeding that may require reoperation, myocardial infarction, stroke, acute renal failure, pneumonia, and stroke.

## 5.5 Changes In Technology Affecting the Risk/Benefit Ratio

Major technical advances in CABG surgery techniques took place during the late 1970s and early 1980s that markedly reduced operative mortality and improved outcomes. The more important of these developments were the introduction of ***cold cardioplegia*** (techniques for cooling and stopping the heart), increased use of the internal mammary artery as a bypass conduit, and the ability to achieve more complete revascularization by inserting greater numbers of bypass grafts. Cold cardioplegia, by reducing the metabolism and oxygen demand of the heart muscle, has reduced the frequency of perioperative myocardial infarction, permitted longer operating times, and reduced operative mortality. Internal mammary artery grafts have been associated with increased graft patency, compared to saphenous vein grafts, and improved long-term

survival. Routine use of ***antiplatelet therapy*** (to reduce the tendency of the blood to clot) has also contributed to improved graft patency. Since the mid-1980s, however, CABG technology has been relatively stable.

## 5.6 Changes in Indications for CABG Surgery

Changes in indications for CABG surgery, and associated changes in utilization rates, have been affected by at least four factors: (1) increased propensity to operate on older and sicker patients; (2) increasing numbers of reoperations in patients who have undergone previous CABG surgery; (3) competition engendered by technological advances and widespread acceptance of PTCA; and (4) studies that have raised questions about the appropriateness of CABG applications.

There is no question that "safer and better" CABG surgery was responsible for broadening clinical indications and the steady growth of CABG utilization during the mid-1980s especially among older patients with more severe heart disease. Operative mortality in these populations is in the 3 to 4 percent range in all but very high risk patients. Reoperations in previous CABG recipients also represent a "new" patient pool which is both at higher risk from CABG surgery and presents unique technical challenges. Some cardiac surgery programs currently include 20 to 30 percent of "redos" in their caseloads.

Countering these stimuli to the growth of CABG surgery has been competition from PTCA. Initially targetted at discrete vascular lesions in single vessel disease, progress in PTCA technology has extended its applications to multivessel and more extensive disease. The dramatic growth of PTCA volume between 1983 and 1990 reflects, in part, substitution of PTCA in patients who previously would have received CABG surgery.

Finally, studies that have suggested relatively high rates of inappropriate CABG surgery may well be affecting selection of patients for the procedure. For example, in the mid 1980s, RAND investigators found that

14 percent of procedures performed in three hospitals in a western state were for inappropriate reasons and another 30 percent were for equivocal reasons according to criteria developed by a panel of experts.

## 5.7 Development of Clinical Guidelines

Concern of over inappropriate use of CABG surgery has led to the development of practice guidelines by four separate groups. In 1989, the PROs implemented pre-admission certification for CABG and other selected high volume surgical procedures based on explicit criteria. Evaluation of this initiative has suggested that it was not cost-effective, however, and it was discontinued in October, 1991. Indirect effects of raising awareness to a possible problem may have been greater than measurable effects of implementation, however.

Three sets of comprehensive practice guidelines for CABG have recently been completed. One of these developed by the American College of Cardiology and American Heart Association has been published. The other two, one by the RAND Corporation and Academic Medical Center Consortium and the other by the Health Care Financing Administration, are currently being field-tested. These practice guidelines will not have affected CABG utilization during the present study but may well affect future utilization.

## 5.8 Summary

CABG technology improved considerably during the 1970s and early 1980s but has been essentially stable since the mid-1980s. Utilization trends in the late 1980s reflect the complex interaction of extension of a "safer and better" procedure to "older and sicker" patients, increasing numbers of reoperations in patients with previous CABG, increasing competition from PTCA, and possible constraints imposed by concerns about the rates of inappropriate CABG surgery.

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# 6.0 DILATATION AND CURETTAGE (D & C) OF UTERUS

## 6.1 Relevant Anatomy and Pathology

The uterus is a hollow organ with two major layers: a muscular layer ***(myometrium)*** and an inner layer ***(endometrium)*** that lines the uterine cavity. The endometrial layer proliferates in response to estrogen, becomes "secretory" in response to progesterone, and then sloughs off when hormones are withdrawn. Such changes occur with each menstrual cycle in premenopausal women; they are also elicited to some degree by estrogen replacement therapy (which is usually given in cyclical doses and with progesterone, to mimic normal menstrual cycles and to induce monthly shedding of endometrial tissue).

Abnormal uterine bleeding has two major causes: disruption of normal hormonal balance; and abnormalities of the endometrium (such as polyps or endometrial cancer) or myometrium (benign muscle growths known as myomas or fibroid tumors).

## 6.2 General Indications

Dilatation and curettage of the uterus is performed as a diagnostic procedure to obtain tissue samples of the endometrium (the inner lining of the uterus) to investigate conditions such as infertility and abnormal vaginal bleeding. In some cases of abnormal vaginal bleeding, D & C may also serve a therapeutic function, by removing the tissue responsible for the abnormal bleeding. Such therapeutic effects are more frequent in premenopausal than postmenopausal women.

In the Medicare population, postmenopausal bleeding is the major indication for D & C. Postmenopausal bleeding may be caused by a number of conditions, including fibroid tumors and endometrial polyps. However, the most serious condition commonly associated with postmenopausal bleeding is endometrial cancer. Endometrial cancer is found primarily in postmenopausal women, and about 8 percent of women with postmenopausal bleeding will be found to have cancer. In order to rule out suspected endometrial cancer, one must

sample the endometrial tissue as completely as possible. D & C has been the standard procedure for complete endometrial sampling. If cancer is found, standard treatment includes hysterectomy.

## 6.3 Description of Procedure

The vagina is prepared with antiseptic solution and the bladder is catheterized. The uterus and ovaries are examined manually by the surgeon to determine size and position, and to rule out the presence of abnormal masses.

Tissue samples are obtained first from the cervical canal. The cervix is then completely dilated, and the endometrial lining of the uterus is scraped thoroughly with a sharp instrument called a curette. Tissue obtained by scraping is sent for examination by a pathologist.

The procedure is usually performed under general anesthesia for several reasons: the procedure, especially dilatation of the cervix, is painful; also, manual examination of the uterus and ovaries is much more satisfactory when the patient's muscles are fully relaxed by general anesthesia. However, adequate pain control can be achieved using local anesthesia (paracervical block) and intravenous sedation; this may be the preferred form of anesthesia in patients with contraindications to general anesthesia, such as cardiac or pulmonary disease. Use of local anesthesia for D & C may therefore be more common among the Medicare population; nevertheless, the vast majority of D & Cs under Medicare are performed under general anesthesia.

Complications of D & C include hemorrhage, infection, perforation of the uterus and uterine adhesions (formation of scar tissue within the uterine cavity).

## 6.4 Changes in Technology Affecting Risk/Benefit Ratio

D & C of the uterus is a very old procedure, having been introduced in 1843. Although its use has grown steadily over the past 50 years, the procedure itself has changed very little. However, utilization of D & C may have been influenced recently by several related technologies, some of which

may serve as partial substitutes and thereby decrease D & C utilization. Other recent technological changes may actually have increased the utilization of D & C.

### 6.4.1 Hysteroscopy

Fiberoptic hysteroscopy is the application of endoscopic technology to uterine disease. The technology has been available for two decades, but was not used widely until the mid-1980s. It is used primarily as a diagnostic tool to inspect the anatomy of the uterine cavity, especially for the presence of focal lesions such as fibroid tumors or polyps, and to obtain small tissue samples. The amount of tissue obtained with hysteroscopic biopsy, however, is limited and the procedure is therefore inadequate to rule out endometrial cancer in postmenopausal women. In this group of patients, hysteroscopy does not substitute for D & C and is more likely to be performed in addition to D & C, allowing the surgeon to search for focal lesions and still obtain an adequate sample of endometrial tissue.

More recently, it has also been used therapeutically, to remove uterine adhesions and polyps, and to reduce the size of fibroid tumors in women of child-bearing age without sacrificing all or part of the uterus. These therapeutic uses are recent, and would have had little effect on Medicare utilization in the 1985-1988 period.

To better visualize the endometrium, the uterine cavity is usually expanded or distended with gas or liquid during hysteroscopy. Since such distention is painful, hysteroscopy is usually performed under general anesthesia.

### 6.4.2 Endometrial Biopsy

The traditional endometrial biopsy is simply a very limited D & C: the surgeon can partially dilate the cervix and, using a curette similar to that for D & C, obtain a small sample of endometrial tissue for pathologic

examination. Because the cervix is only slightly dilated, the procedure can be performed without anesthesia.

Since they reflect the diffuse cyclical effects of estrogen and progesterone, incomplete samples obtained from endometrial biopsy are often sufficient to diagnose the cause of abnormal bleeding in premenopausal women, in whom such bleeding is most frequently associated with hormonal imbalance. In older women, however, the small samples obtained with standard biopsies are inadequate to rule out endometrial cancer and cannot be used as substitutes for D & C in the evaluation of abnormal bleeding.

Newer endometrial sampling technologies have been developed, however, in which the use of suction replaces or complements the mechanical scraping of the standard D & C. These aspiration sampling techniques use a long thin hollow tube (also called a "curette," but very different from the sharp instrument used in a D & C). Aspiration curettes may be reusable or disposable, and may be made of stainless steel or plastic. Suction may be applied by an external pump or simply by a large syringe. A number of proprietary aspiration curettes are marketed, such as Vabra, Abradul, Karman, Pipelle, Novak, and Masterson.

Since aspiration curettes are very thin, the cervix need not be dilated, and aspiration biopsy or curettage can be performed in an office setting with no anesthesia. Its diagnostic accuracy is similar to that of the D & C, with 96 percent to 98 percent accuracy in diagnosing cancer of the endometrium, according to one study. However, controlled studies comparing aspiration techniques with standard D & C are difficult to perform. (One would prefer to compare both procedures in the same subject. However, each technique can remove abnormal tissue and thus limit the diagnostic accuracy of the second procedure.) In the absence of controlled comparisons, many gynecologists rely on D & C as the standard in cases where endometrial cancer is suspected. Although aspiration curettage may be performed initially as an office procedure (because it requires no anesthesia, advanced scheduling, or patient preparation), most postmenopausal women with abnormal bleeding will still receive a standard D & C.

Aspiration sampling techniques are more likely to substitute for D & C in postmenopausal women receiving estrogen therapy. Replacement estrogen is being used increasingly to minimize osteoporosis in postmenopausal women. However, estrogen therapy increases both the risk of endometrial cancer and the incidence of postmenopausal bleeding. Women taking replacement estrogen for osteoporosis are more likely to undergo some sort of endometrial sampling procedure. If bleeding occurs, a D & C is usually performed. In the absence of bleeding, many women will be requested to undergo routine endometrial monitoring, once before beginning estrogen therapy and then perhaps yearly. For these latter women, aspiration curettage may be a satisfactory substitute for standard D & C. Thus, although estrogen replacement therapy may have increased the need for D & C, the increase may be moderated by the substitution of aspiration sampling methods.

## 6.5 Shifts of Procedures to Ambulatory Settings

In the 1980s, pressure by third-party payors caused D & Cs to shift from primarily inpatient to primarily outpatient procedures. Today, the majority of D & Cs, even for Medicare patients, are performed in ambulatory surgery settings. Only those patients with increased surgical risk from comorbid conditions are likely to be admitted for D & C.

Although the majority of D & Cs are performed under general anesthesia, the procedure itself is brief and patients therefore recover quickly from the effects of anesthesia. Most patients can be discharged to home a few hours after the procedure with oral medication for pain control.

## 6.6 Development of Clinical Guidelines for D & C

The American College of Obstetricians and Gynecologists (ACOG) is the organization with greatest influence on physician practice in Ob-Gyn. ACOG publishes a series of "technical bulletins" covering specific conditions. However, the College states that these bulletins do "not define a standard of

care." Rather, they "present recognized methods and techniques of clinical practice for consideration by obstetrician-gynecologists for incorporation into their practices."

There is no single technical bulletin that covers all aspects of the D & C procedure. Instead, D & C is discussed in several bulletins in the context of specific conditions. One bulletin relevant to the Medicare population is that published for estrogen replacement therapy in June, 1986. This bulletin states that aspiration curettage is an acceptable procedure for the routine evaluation of bleeding in women on estrogen therapy, and that D & C is necessary only when aspiration curettage is unsuccessful, or when endometrial abnormalities have been demonstrated by a previous endometrial sampling procedure. The bulletin also advocates yearly endometrial biopsy during estrogen replacement therapy in specific circumstances.

The influence of ACOG technical bulletins on Ob-Gyn practice is difficult to evaluate. The College publishes two major Ob-Gyn journals; however, the bulletins were not routinely sent to journal subscribers until very recently, and are therefore not generally available in medical libraries.

## 6.7 Summary

D & C is an old and stable technology. Indications for its use in the Medicare population are also stable; however, the need for D & C in post-menopausal women is probably steadily increasing due to increased use of replacement estrogen therapy. Although hysteroscopy and aspiration sampling techniques can be substituted for D & C for many conditions, these procedures are less satisfactory substitutes in post-menopausal women because the risk of endometrial cancer requires more complete examination of endometrial tissue. D & Cs have become primarily ambulatory surgical procedures, with the changeover occurring in the mid-1980s.

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# 7.0 TOTAL HIP REPLACEMENT (THR)

## 7.1 Relevant Anatomy and Pathology

Mechanically, the hip is a relatively simple ball-and-socket joint. The ball is the rounded head of the ***femur***. The socket is formed by the ***acetabulum***, a cup-shaped depression in the pelvic bones, and by the strong ***capsule*** of the hip joint, which extends from the acetabulum to completely enclose the femoral head. The capsule is strengthened by ligaments connecting the acetabulum and femur. The ball-and-socket construction permits a wide range of motion in all directions.

The opposing joint surfaces of the acetabulum and femoral head are covered with cartilage so that the surfaces glide smoothly against one another. Damage to the joint cartilage is most commonly caused by two forms of arthritis. ***Osteoarthritis*** (OA), also known as ***degenerative joint disease*** (DJD), is the most prevalent type. OA is uncommon below the age of 35, and increases in prevalence with age. Almost 70 percent of persons age 65 or over have radiologic evidence of OA, and up to 40 percent of these may have some symptoms. Its exact etiology is unknown, but a major contributing factor is excessive wear on joints (e.g., from occupational or recreational activities, obesity, or slight misalignment of bones leading to uneven wear). When exposed to excessive wear over prolonged periods, joint cartilage softens and thins, and eventually erodes completely, exposing bone at the joint surface. Usually only one or a few joints are affected. Symptoms typically include a deep ache relieved by rest, and stiffness after resting. When OA affects the hip, the patient at first notices aching in the groin, buttock, or thigh, aggravated by activities such as prolonged walking. As the disease progresses, the patient may need to use a cane or crutch to transfer weight away from the affected hip. Advanced OA of the hip can severely limit mobility, preventing the patient from climbing stairs or even from walking more than a few feet.

Rheumatoid arthritis (RA) may also affect the hip joint. RA is much less common than OA, affecting only 1 or 2 percent of the general population. Although RA may occur at nearly any age, most patients develop their first symptoms between the ages of 30 and 50. Women are more often affected than men. Unlike OA, RA is a systemic illness, affecting many body systems in addition to the joints: patients with RA may have anemia, lung disease, skin nodules, enlargement of lymph nodes and spleen, and other problems. RA typically affects several joints at the same time, usually in a symmetrical distribution (e.g., both knees, and the wrists and fingers of both hands). RA is more likely than OA to cause bilateral hip disease. Although OA and RA differ in many respects, both forms of arthritis can lead to severe restriction of mobility when the hip joint is affected.

In addition to arthritis, the other important cause of hip disease in the elderly is fracture of the femur at or near the femoral head. Hip fractures occur more commonly in the elderly, and most commonly in elderly females, because of the higher prevalence of ***osteoporosis***. Osteoporosis is a generalized decrease in bone density and strength that affects both men and women with increasing age; however, it occurs earlier and more rapidly in women, with accelerated bone loss beginning at menopause. In patients with significant osteoporosis, fractures can occur with relatively minor trauma in areas such as the vertebrae, wrist, upper arm, lower leg, and hip. Hip fractures are of particular concern in the elderly because they frequently cause a permanent decrease in mobility, even with excellent treatment and healing. Two complications of hip fracture are associated with marked reductions in function restriction of activity. First, osteoporotic bones may not heal properly following a fracture, a condition referred to as ***non-union***. If proper healing does not occur, the affected leg will not be able to bear weight. Second, most of the blood supply to the femoral head passes through the ***femoral neck***, an area of decreased diameter between the head and shaft of the femur. Fractures of the femoral neck may sever these fragile vessels, often resulting in death of bony tissues in the head. Death of bone following loss of blood supply (referred to as ***avascular necrosis*** or ***osteonecrosis***)

leads to severe pain with loss of hip function. Non-union and avascular necrosis are serious complications and can result in permanent loss of mobility without appropriate surgical treatment.

## 7.2 Indications for Total Hip Replacement

In rheumatoid arthritis, the goal of medical therapy is to control the inflammatory process which causes joint pain, joint destruction, and other symptoms. Patients are usually treated with non-steroidal anti-inflammatory agents (aspirin, ibuprofen, indomethicin, and others), oral steroids (prednisone), or other drugs.

In osteoarthritis, therapy is directed to controlling pain with analgesics (e.g., acetominophen) or non-steroidal anti-inflammatory agents, as well as eliminating factors which may cause unnecessary stress on the hip joint (weight reduction in obesity; proper balance of activity and rest; use of corrective shoes or a cane for walking, if necessary). Application of heat may also be helpful.

Total hip replacement in arthritis (whether RA or OA) is reserved for patients with severe pain or marked loss of mobility who have not responded to conservative measures. It is more suitable for patients over age 60, who typically engage in less vigorous physical activity and will place lower stress on the prosthesis.

Patients with hip fractures must be treated promptly to minimize the risk of non-union of bone fragments or of avascular necrosis from loss of blood supply. Adequate fixation of bone fragments can be achieved in most cases with pins, nails, screws, or plates. In the long run, however, successful treatment of hip fractures depends on the ability of the patient's bones to heal themselves. In patients at significant risk of non-union or avascular necrosis, and in patients with significant pre-existing hip disease from OA or RA, total hip replacement may be the appropriate initial treatment for hip fracture.

## 7.3 Description of Total Hip Replacement

Under general anesthesia, an incision is made in the side of the thigh and buttock. The muscles overlying the hip are cut to expose the joint capsule. The capsule is opened, and the femoral head is dislocated from the acetabulum. The femoral head and neck are removed with an oscillating saw. The cup-shaped acetabulum is enlarged and cleaned of bone and cartilage fragments. The ***acetabular component*** of the hip prosthesis is a cup made of two layers: a metallic outer shell, and an inner lining of polyethylene, which provides a smooth surface analogous in function to cartilage. The acetabular component is inserted into the pelvic bones and fixed, either with cement or with a bone graft. The ***femoral component*** of the hip prosthesis replaces the femoral head and neck and is made entirely of metal. The stem of the femoral component is driven into a channel created in the shaft of the femur and is fixed with cement or bone grafts, leaving the prosthetic head and neck exposed. The round metallic head is inserted into the polyethylene socket of the acetabular component, recreating the ball-and-socket joint; the joint capsule, muscles, and tendons are reattached; and the wound is closed.

Following surgery, patients can be discharged to home within 10 days, but will need to undergo a lengthy rehabilitation process, including 6 to 12 weeks of walking with crutches (to avoid placing too much stress on the new hip prosthesis) and several months of progressive exercise to regain leg strength. Following rehabilitation, the vast majority of patients will have excellent pain relief and nearly normal hip function, with the ability to walk, climb stairs, get in and out of a car, and so forth. However, activities involving repetitive impact on the hip (such as jogging or playing tennis) may lead to early loosening of the prosthesis.

Early complications of total hip replacement include intra-operative damage to nerves, and post-operatively infection and development of blood clots ***(deep venous thrombosis)*** in the leg. In patients with deep venous thrombosis, a blood clot may travel from the leg to the lungs ***(pulmonary***

***embolism***), causing shortness of breath, chest pain, and even death. Late complications include loosening or failure (e.g., fracture) of one or both prosthetic components.

## 7.4 Changes in Technology Affecting Risk/Benefit Ratio

The hip is a simple joint, and mechanically satisfactory hip prostheses have been available for three decades. Recent technological advances have been focussed on reducing the incidence of complications following total hip replacement.

One of the most frequent and serious complications is loosening of prosthetic components. Until the 1980s, all hip prostheses were fixed to bone by acrylic cement. Unfortunately, this cement begins to fail after a period of time. On X-ray, 30 to 50 percent of cemented femoral components, and 10 to 15 percent of cemented acetabular components, will show evidence of loosening after ten years. Many of these patients will experience symptoms, such as pain on walking, which increase in severity as loosening progresses. Ten to thirty percent of patients with hip replacements will require reoperation after 10 years, mostly because of loosening.

To solve the problem of loosening, two different approaches have been followed in the 1980s. One is to search for improved cements which last much longer. The second is the development of ***cementless prostheses***. Two types of cementless prostheses are now in use. In ***porous-coated*** prostheses, the surfaces exposed to bone are covered with tiny metal beads or wires, allowing bone to bond to the prosthesis in much the same way that a bone fracture heals. Porous-coated prostheses require normal bone growth for good bonding, and are therefore more appropriate for younger patients. In ***press-fit*** prostheses, slots in the bone are cut to precisely mirror pins in the prosthetic surface, and the two surfaces interlock when they are pressed together. This method requires more technical skill and is not performed by all surgeons. Like porous-coated, press-fit prostheses are of greater benefit to younger patients.

A second, infrequent complication of total hip replacement is fracture of the femoral component. Over time, especially with partial loosening, small stress fractures may occur in the metal and grow until the prosthesis breaks completely. Newer, stronger metallic alloys are designed to reduce the incidence of prosthetic fracture.

Changes in medical therapy have occurred as well. Newer antibiotics and routine use of prophylactic antibiotics have reduced the incidence of post-operative infection. Routine use of anticoagulants has reduced the frequency of deep venous thrombosis and pulmonary embolism.

However, these advances in medical and surgical technology have probably had only a minor impact on utilization of total hip replacement in the elderly. An equally important influence may be an increase in the number of surgeons trained to perform total hip replacement. Nearly all orthopedic surgeons now gain some experience with THR during their residency training, and post-residency fellowships in THR are also available.

## 7.5 Changes in Indications for Hip Replacement

The indications for total hip replacement have been stable. Most hip replacements are done in patients with severe hip pain that limits their mobility. Patients with osteoarthritis outnumber those with rheumatoid arthritis by about ten to one. A small number of THR procedures are revisions of old hip prostheses in patients with loosening, and an even smaller number are performed as primary treatment for hip fractures.

Although the indications for THR have not changed, it is possible that there has been some lowering of the threshold for surgery in terms of pain and loss of function, and that patients undergoing THR today may have slightly less severe disease than those of ten years ago. Nevertheless, total hip replacement is still reserved for patients with severe hip pain or dysfunction.

## 7.6 Shifts of Procedures to Ambulatory Settings

Total hip replacement is never performed in ambulatory settings.

## 7.7 Development of Clinical Guidelines for Total Hip Replacement

In 1990, the American Academy of Orthopaedic Surgeons published a set of six "clinical policies" on orthopedic conditions, including femoral neck fracture and osteoarthritis of the hip. The guidelines for femoral neck fracture state that total hip replacement may be appropriate for patients with hip fracture "who, in addition to the fracture, show evidence of osteoarthritis or rheumatoid arthritis of the hip or associated disorders," as well as for some patients "with increased risk for developing nonunion or osteonecrosis of [the] femoral head." The guidelines for osteoarthritis list total hip replacement as a therapeutic option, but conditions in which it is appropriate are not specified. Although these clinical policies were made available to some physicians beginning in 1989, it is unlikely that they had any measurable effect on utilization of total hip replacement.

## 7.8 Summary

Several non-price factors are likely to have favored increased utilization of total hip replacements in the late 1980s. First, the supply of physicians trained to perform the procedure has increased, since THR has been a standard part of the training in most orthopedic residency programs since the early 1980s. Secondly, the pool of patients for whom THR is indicated has probably increased for three reasons: the threshold for performing hip replacement has probably been lowered slightly; the number of patients requiring repeat hip replacements (primarily because of loosened prostheses) is growing; and a small number of patients are receiving hip replacements as primary therapy for hip fractures.

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# 8.0 TOTAL KNEE REPLACEMENT (TKR)

## 8.1 Relevant Anatomy and Pathology

In contrast to the hip, the knee is a complex joint. Two weight bearing bones, the ***femur*** and the ***tibia***, meet at the knee. The principal motion at the knee is flexion and extension, and thus the knee superficially resembles a hinge. Unlike a hinge, however, the femur and tibia are not fixed rigidly to one another, but are held together by ligaments which allow not only flexion but limited rotation and side-to-side movement. The ***anterior*** and ***posterior cruciate ligaments*** bind the knee together and limit forward and backward movement. The ***medial*** and ***lateral collateral ligaments*** stabilize the knee on each side and limit side-to-side motion. In addition, the knee contains a third bone, the ***patella***, which rides over the femur during flexion and extension. Cartilage covers the joint surfaces of the femur, tibia, and patella. In addition, two cartilaginous discs, the ***medial*** and ***lateral menisci***, act as cushions between the femur and tibia.

The knee is affected by arthritis in much the same way as the hip. ***Osteoarthritis*** (OA), also called ***degenerative joint disease*** (DJD), most commonly affects the knees. It is more common in older patients. Contributing factors are excessive wear on the joints, obesity, and anatomical misalignments which cause uneven wear (such as "bow-leg" or "knock-knee" deformities). In OA, cartilage softens and thins, and may eventually erode completely, exposing bone at the joint surface. The medial and lateral menisci can tear as a result of degenerative disease, creating loose fragments of cartilage in the joint. Abnormal bone growth also occurs ***(bone spurs)***. Symptoms typically include deep aching, stiffness, and (in advanced cases) limitation of movements such as using stairs, getting out of chairs, or even walking. Loose fragments of bone or cartilage may cause "locking" of the knee or sudden increases in pain.

***Rheumatoid arthritis*** (RA) is much less common than osteoarthritis. Unlike OA, it is a systemic illness, affecting many body systems in addition to the joints. RA nearly always affects both knees at the same time, causing

painful swelling and destruction of joint cartilage. Like OA, RA affecting the knees can severely restrict mobility.

## 8.2 Indications for Total Knee Replacement

Osteoarthritis of the knee is treated conservatively by a proper balance of rest and activity; by oral analgesics or non-steroidal anti-inflammatory agents; by application of moist or dry heat; and by weight reduction and correction of anatomic misalignment (e.g., by orthopedic shoes) if indicated. Injections of corticosteroids into the joint space are also sometimes helpful.

Medical therapy of rheumatoid arthritis attempts to control the generalized inflammatory process causing symptoms in joints and other areas. One or more agents from several classes of drugs are used, including non-steroidal anti-inflammatory agents (aspirin, ibuprofen, etc.); oral corticosteroids (prednisone); and other drugs (gold compounds, immunosuppressive agents).

Arthroscopic surgery can also offer some relief to patients with arthritis of the knee. Bone spurs and fragments of cartilage can be removed arthroscopically. Uneven areas of cartilage can be abraded to eliminate irregularities, and torn menisci can be removed. Arthroscopic surgery, however, is a temporizing approach, since it does not arrest the continuing destruction of joint cartilage by either degenerative (OA) or inflammatory (RA) processes. Patients may have improvement or elimination of arthritic symptoms for months or a few years after arthroscopic surgery, but most will require further medical or surgical therapy.

In total knee replacement, the degenerative or inflammatory arthritic process is halted because the substrate (joint cartilage) is completely removed and replaced. However, because TKR is a major surgical procedure involving significant risks, costs, and rehabilitation, it is indicated only for patients with severe pain and/or marked restriction of activity who are not helped by more conservative medical therapy. It is usually reserved for older, less active patients, since vigorous physical activity can lead to loosening and failure of the knee prosthesis.

## 8.3 Description of Total Knee Replacement

The joint capsule is exposed and opened. Both collateral ligaments are preserved. Because it significantly contributes to joint stability, the posterior cruciate ligament is usually kept as well. However, the anterior cruciate ligament is generally cut to facilitate access to the joint. The joint surfaces of the femur and the tibia are trimmed and shaped with a saw and other instruments to accommodate the prosthetic joint surfaces.

The knee prosthesis itself consists of three separate parts: the ***femoral, tibial*** and ***patellar*** components. Essential to knee replacement, the femoral and tibial components are extremely durable susbstitutes for the biologic joint surfaces of the femur and tibia, with nearly the same shape. These two components are attached only to bone, not to each other; however, once installed, they will be held firmly in contact with each other by the knee's own ligaments (in most cases, by the two collateral ligaments and the posterior cruciate). The femoral and tibial prosthetic components can be attached to bone by cement or by one of two cementless techniques. The patellar component is used at the discretion of the surgeon. In patients with RA, the patella is usually replaced by a polyethylene button. In OA, it may or may not be replaced, depending on the condition of the patellar cartilage and how well it glides against the femoral prosthesis.

Following surgery, most patients have excellent relief from pain and nearly normal range of motion in the knee. A rehabilitation period lasting several months is required to regain strength in the leg muscles.

Early complications of total knee replacement include infection, and blood clots in the leg ***(deep venous thrombosis)*** which may travel to the lung ***(pulmonary embolism)***, causing shortness of breath, chest pain, or even death. The risk of these complications is reduced by the prophylactic use of antibiotics and anti-coagulants.

As with total hip replacement, prosthetic failure is a potential long-term complication of knee replacement. The patella or patellar prosthesis may become dislocated or may fracture. In about five percent of

TKRs, one of the other components (almost always the tibial prosthesis) will loosen from bone within ten years, requiring surgical revision of the knee replacement.

## 8.4 Changes in Technology Affecting Risk/Benefit Ratio

Because the knee is mechanically more complex than the hip, satisfactory knee prostheses took much longer to develop. Extensive computer-assisted analysis and laboratory testing were required to understand the mechanical forces transmitted through the knee during normal motion, and to design prosthetic components and materials which could withstand these forces over long periods of time, while offering at the same time both stability and a normal range of motion. Early knee prostheses used in the 1960s and 1970s were hinged; this rigid connection between the femur and tibia resulted in high rates of loosening of prostheses. In modern knee prostheses, the only attachments between the femur and the tibia are the natural ligaments. Other design changes affected the distribution of load as body weight is transferred from the femur to the tibia. These improvements occurred largely in the early and mid-1980s. Today, knee prostheses provide outcomes that are at least as reliable and satisfactory as hip prostheses in relieving pain and allowing nearly normal mobility. These improvements in the design of knee prostheses markedly increased the benefits of total knee replacements, and are directly linked to increased utilization of the procedure in the late 1980s.

Of course, improvements in medical therapy contributed to the improved outcomes of TKR by reducing the risk of deep venous thrombosis and pulmonary embolism through the use of anti-coagulants, and by reducing the risk of post-operative complications with routine use of prophylactic antibiotics.

As with total hip replacement, some controversy exists over the best way to attach knee prostheses to bone. Both porous and press-fit cementless prostheses have been tried in the knee with varying success. Experience has shown, however, that cemented knee prostheses are well suited to older, less active patients, and development of cementless techniques is not expected to affect utilization substantially in the older population.

## 8.5 Changes in Indications for Knee Replacement

Total knee replacement is indicated in only a limited number of conditions, primarily osteoarthritis and rheumatoid arthritis. In this sense, indications have not changed. However, the availability of reliable, mechanically satisfactory prostheses means that TKR is no longer thought of as an experimental therapy or as a last resort for patients with severe pain. There has thus been a dramatic increase in the number of patients for whom this surgical treatment is appropriate.

## 8.6 Shifts of Procedures to Ambulatory Settings

Total knee replacement is never performed in ambulatory settings.

## 8.7 Development of Clinical Guidelines for Total Knee Replacement

No guidelines have been published regarding the use of total knee replacement.

## 8.8 Summary

Total knee replacement is a technology which has offered satisfactory outcomes only since the mid-1980s. It is indicated in only a small percent of patients with osteoarthritis and rheumatoid arthritis - those whose mobility is limited by severe pain unresponsive to medical therapy. However, since one of these conditions (osteoarthritis) is very common in the elderly, the number of Medicare patients who may benefit from this procedure is considerable. Recent increases in the utilization of this procedure are attributable to technological improvements since 1980 which offer improved quality of life to those with disabling arthritis of the knee.

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# 9.0 KNEE ARTHROSCOPY

## 9.1 Relevant Anatomy and Pathology

The knee is a complex joint with several important structures. The ***femur*** and the ***tibia*** are long, weightbearing bones which meet at the knee. The ***patella*** is a non-weightbearing bone which is attached to muscle tendons and glides over the femur at the knee. The joint surfaces of each of these three bones is covered by cartilage which can be damaged by trauma, inflammation, or degeneration associated with age and excessive wear.

The knee is divided into ***medial*** and ***lateral compartments*** by two thick ligaments which cross the middle of the knee from front to back. These are the ***anterior*** and ***posterior cruciate ligaments,*** which bind the femur and the tibia together and limit their movements against one another. The medial and lateral compartments each contain a ***meniscus,*** a cartilaginous disc which helps absorb the impact of the femur against the tibia. Like the cartilage which lines bone surfaces, these ***medial*** and ***lateral menisci*** can be damaged by trauma, inflammation, and degenerative processes.

The knee joint is stabilized on each side by the ***medial*** and ***lateral collateral ligaments,*** which prevent excessive side-to-side bending. The knee is surrounded by a fibrous ***joint capsule.*** The capsule is lined by a ***synovial membrane*** which secretes ***synovial fluid*** (joint fluid).

## 9.2 Indications for Knee Arthroscopy

In older patients, the most common derangement in the knee is ***osteoarthritis*** (OA), also known as ***degenerative joint disease*** (DJD). Common risk factors for the development of OA are obesity and anatomical abnormalities of the legs ("bow-leg" and "knock-knee" deformities). Osteoarthritis can usually be diagnosed simply from the patient's complaints of stiffness and aching, and from a physical exam characterized by pain and "cracking" in the knee, without evidence of inflammation or infection.

The knee may also be affected by ***rheumatoid arthritis*** (RA), which is less common than OA. Most elderly patients with RA will have multiple joint involvement, evidence of swelling and inflammation on physical examination, and histories of symptoms and treatment going back several years.

Progression of arthritis (whether RA or OA) can be followed by physical examination and by routine X-rays of the knee, which may demonstrate abnormal bone formation and erosion of bone, both common processes in arthritis. These diagnostic techniques are adequate for the care of arthritic patients with uneventful courses who are responding adequately to non-surgical therapy.

However, X-ray studies (whether plain films or CT) give very little direct information about the condition of ligaments or cartilage. MRI scanning (which does not use X-rays) does image joint cartilage and ligaments, and has been used successfully to diagnose meniscal tears and torn cruciate or collateral ligaments (e.g., following sports injuries). Knee arthroscopy, however, is recognized as the definitive technique for examining cartilage and ligaments within the knee. The arthroscopist can see directly virtually all aspects of surface structures within the knee. Among the elderly, this invasive procedure is most useful diagnostically in arthritic patients with moderate to severe symptoms that do not respond well to conservative (non-surgical) therapy, and in those who have a dramatic worsening of symptoms. In addition, arthroscopy can be used therapeutically in the knee to remove abnormal cartilage or bone that may be causing severe pain or interfering with activity. Because of this therapeutic potential, arthroscopy serves as a nearly complete substitute for open surgery of the knee ***(arthrotomy)***, and can be used to postpone the need for total knee replacement.

## 9.3 Description of Knee Arthroscopy

The arthroscope, like other endoscopes, is a flexible tube containing glass fibers which transmit light from an external source to its tip, illuminating the area under examination, and then return an image to the surgeon. The tip of the arthroscope can be controlled by the surgeon to provide a wide range of view within the joint.

Arthroscopy may be performed using a variety of anesthetic techniques. Most commonly, a combination of local anesthesia and intravenous sedation are used. General anesthesia may be used in patients who are extremely anxious.

When general or regional anesthesia is not employed, a local anesthetic is injected into the skin at three sites: on either side of the knee (the ***medial*** and ***lateral ports***), and the upper border of the patella. A needle is then inserted above the patella so that the joint can be irrigated as needed by saline solution. Small incisions, about one half inch long, are made at the medial and lateral ports. The arthroscope is inserted first through the lateral port and later through the medial port. (The knee must be entered in two different places because the cruciate ligaments divide the knee into two separate compartments.) Ligaments, joint cartilage, and the meniscus in each compartment is examined visually. Therapeutic maneuvers may be performed by inserting instruments through one of the ports. For example, forceps may be used to extract bits of bone or cartilage; a rotating burr may be used to grind down roughened cartilage. Sterile saline solution from the third port is used to flush the joint periodically to clear bloody fluid and debris. When all diagnostic and therapeutic arthroscopic procedures are complete, the three small incisions are closed with sutures or with adhesive strips. When arthroscopy is performed for diagnosis only, it can be completed in thirty minutes or less. Therapeutic arthroscopy requires somewhat longer, but is still a relatively brief procedure.

Patients are usually able to walk as soon as they have recovered from effects of medication (intravenous sedation, or general or regional anesthesia), usually within a few hours. Most will have postoperative pain, which can be treated by applying ice, elevating the leg, and using oral analgesics. Most patients will also need to use crutches for support for one or more days; weightbearing will be more painful in those who have undergone more extensive therapeutic procedures.

Complications of arthroscopy include infection, formation of blood clots in the leg *(**deep venous thrombosis**, or **DVT**)* which occasionally travel to the lung *(**pulmonary embolism**)*, and injury to nerves as they cross the knee area. These complications, however, are infrequent. Intravenous antibiotics are

often used during arthroscopy to prophylax against infection. No particular precautions are needed for DVT, since the surgical procedure is brief and patients are up and about within 12 to 24 hours. Good surgical technique minimizes the incidence of nerve damage.

A rare complication of arthroscopy is ***reflex sympathetic dystrophy*** (RSD), a poorly understood condition characterized by chronic leg pain and lasting up to a year or more. Its cause is unknown. When it occurs, it is treated with varying success by nerve blocks, physical therapy, and anti-depressants.

## 9.4 Changes in Technology Affecting Risk/Benefit Ratio

Several improvements in the design of the arthroscope itself have altered the risk/benefit ratio of the procedure. Arthroscopes used in the knee are now less than half a centimeter in diameter, requiring smaller incisions which heal faster. Videoscopic arthroscopes have been in use since the early 1980s; technological improvements since then have reduced the video component of these scopes to the size of a cellular telephone. Procedures performed with videoscopes can be displayed on monitors, allowing physicians in training (and patients if they wish) to view any abnormal findings and therapeutic maneuvers. Such procedures can also be videotaped for retrospective review of findings and treatment. Since about 1986, printers have been available which attach to the video cameras, allowing "freeze frame" images of the procedure to be printed instantly, again improving communication with patients and other physicians. However, because they are significantly more expensive than standard arthroscopes, videoscopes are usually found only in teaching hospitals and large community hospitals.

The previously described technological advances, however, are unlikely to have had a great influence on utilization of arthroscopy. More significant in this regard is the development of new therapeutic techniques which extend the clinical applications of arthroscopy. Prior to 1985, arthroscopy was being used to remove loose fragments of cartilage, or to trim the frayed edges of degenerative menisci ***(subtotal meniscectomy)***. Since then, improvements

have occurred in instruments used within the knee - the scissors, trimmers and grabbers used within the knee joint - which have widened the range of knee procedures which can be performed arthroscopically.

The most important new therapeutic use in the Medicare population is ***abrasion arthroplasty***. In this procedure, a rotating burr is used to remove degenerative cartilage from joint surfaces in the knees of patients with OA. The cartilage is abraded until bone can be seen. Within several weeks, the bared areas of bone will have been completely resurfaced with a smooth coat of fibrocartilage which, although not as durable as normal joint cartilage, will usually allow pain-free mobility of the knee joint for an extended period of time. Abrasion arthroplasty is most successful when only limited areas of cartilage are treated. For more extensive disease, total knee replacement may be appropriate. Furthermore, abrasion arthroplasty is a temporizing measure: most patients will eventually have recurrence of joint pain as the degenerative process continues. Despite these limitations, abrasion arthroplasty has been an increasingly popular procedure, since severe knee pain can often be alleviated by this ambulatory surgical procedure for two years or more, postponing the need for more extensive surgery such as knee replacement.

Another relatively new technology, MRI, may decrease the utilization of knee arthroscopy by substituting for it. MRI is able to image ligaments and cartilage since it does not use X-rays. (Bone, because it is much more radiopaque, obscures adjacent cartilage and ligaments in X-ray studies.) Clinical research has been conducted comparing MRI with arthroscopy in diagnosing non-bony disorders in the knee. One study found that in patients with meniscal tears, MRI was highly sensitive, detecting abnormalities in 90 to 97 percent of patients with tears. However, its specificity was lower (77 to 87 percent). Thus, while a normal MRI scan may help avoid arthroscopy, patients with abnormal scans may still require arthroscopy to determine the exact nature of the abnormality. The precise role of MRI in diagnosing disorders of the knee is still being defined, and most physicians still regard arthroscopy as the "gold standard." Furthermore, MRI is a strictly diagnostic tool; when pathology amenable to arthroscopic intervention is suspected,

arthroscopy is preferable to MRI. Finally, since the cost of an MRI scanner exceeds that of an arthroscope by orders of magnitude, arthroscopy is more widely available than MRI. For these reasons, MRI would have caused only a limited decrease in the utilization of knee arthroscopy before 1989.

## 9.5 Changes in Indications for Knee Arthroscopy

In the Medicare population, arthroscopy is still used primarily in patients with osteoarthritis and in those with rheumatoid arthritis. Thus, the number of disease entities in which arthroscopy is used has not changed. However, the applications for arthroscopy within these two diseases have broadened considerably with the development of therapeutic arthroscopic procedures.

## 9.6 Shifts of Procedures to Ambulatory Settings

Because arthroscopy is a brief procedure requiring minimal restriction in activity postoperatively, it has always been performed to some extent as an ambulatory procedure. However, as recently as 1985, about half of patients undergoing the procedure were hospitalized for one night postoperatively. Because of changes in payer regulations since the mid-1980s, arthroscopy is now performed almost exclusively as an ambulatory procedure. Ordinarily, patients are admitted only for medical complications such as cardiac arrhythmia or markedly elevated blood sugar.

## 9.7 Development of Clinical Guidelines for Knee Arthroscopy

No clinical guidelines have been published for knee arthroscopy.

## 9.8 Summary

Knee arthroscopy has achieved wide acceptance as both a diagnostic and therapeutic tool for Medicare patients with osteoarthritis and rheumatoid

arthritis. When it was introduced, it provided an excellent alternative to the unsatisfactory extremes of plain X-rays and open arthrotomy as diagnostic procedures. Since its introduction, it has also almost entirely replaced open arthrotomy as a therapeutic technique in elderly patients, since the abnormalities associated with OA and RA in the knee (diseased cartilage, abnormal bony growths, and thickened joint lining) can all be treated arthroscopically. While MRI has been a partial substitute as a diagnostic tool, any resulting decrease in the diagnostic use of arthroscopy is likely to have been outweighed by growth in therapeutic uses, such as abrasion arthroplasty.

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# 10.0 PERMANENT CARDIAC PACEMAKER IMPLANTATION

## 10.1 Relevant Anatomy and Pathology

In the normal heart, cardiac impulses are initiated in the right atrium by a group of cells with intrinsic pacemaker activity known as the sino-atrial ***(SA)*** node. Each electrical impulse generated by the SA node spreads rapidly throughout the right and left atria, stimulating atrial contraction. It then reaches the atrio-ventricular ***(AV)*** node, a specialized conducting tissue which slows the electrical impulse substantially. The impulse is finally transmitted to the ventricles, stimulating ventricular contraction.

The right and left atria act somewhat like reservoirs for blood returning to the heart. Normal contraction of the atria results in rapid filling of the ventricles, allowing for more efficient cardiac function. Blood circulation throughout the lungs and the body is the result of forceful contraction of the right and left ventricles.

When the SA node is functioning normally, the heart rate is influenced by the nervous system and by circulating hormones, and increases with exercise and stress. When the AV node and other components of the conduction system are functioning normally, contractions of the atria and ventricles are coordinated, providing rapid ventricular filling and increased cardiac output.

## 10.2 Indications for Permanent Cardiac Pacemaker Implantation

The most common indications for pacemaker insertion are dysfunction of the SA node ("sick sinus syndrome") and AV node disease. In ***SA node dysfunction***, the intrinsic cardiac pacemaker discharges erratically, at times causing an abnormally slow heart rhythm (bradycardia, or heart rate less than 60 beats per minute) and at times a rapid rhythm (tachycardia, or heart rate over 100). Because of its distinctive conduction properties, a properly functioning AV node can often mitigate the effects of tachycardia caused by SA node disease, for example by transmitting only every other impulse to the ventricles. Bradycardia, however, is likely to significantly reduce blood

flow to major organs, resulting in symptoms such as dizziness, lightheadedness, exercise intolerance, congestive heart failure, and syncope (sudden, brief periods of unconsciousness). Pacemakers are routinely used in patients with symptomatic bradycardia; a heart rate under 60 without symptoms is not a sufficient indication for pacemaker insertion.

There are three categories of ***AV node dysfunction***. In ***first-degree AV block***, conduction of electrical impulses to the ventricles is delayed abnormally. In ***second-degree block***, some impulses (perhaps every other or every third) are blocked from reaching the ventricles. In ***complete (third-degree) heart block***, no impulses from the intrinsic pacemaker reach the ventricles.

Even when intrinsic pacemaker rate is normal, AV node disease can substantially decrease the impulses transmitted to the ventricles, resulting in bradycardia or pauses, and (as with bradycardia caused by SA node dysfunction) causing dizziness, lightheadedness, syncope, or other symptoms. The incidence of AV node dysfunction increases with age; the condition also occurs in many patients following acute myocardial infarction. It can also be caused by many drugs used to treat congestive heart failure (digitalis) or to control angina and hypertension (beta-blockers such as propanolol; calcium channel blockers such as verapamil and nifedipine). Such drug-associated AV dysfunction is more common in the elderly, many of whom may already have age-associated impairment of conduction.

First-degree heart block by itself is never an indication for permanent pacing. Pacemakers are indicated in patients with symptomatic bradycardia resulting from second- or third-degree heart block, and also in certain asymptomatic patients with heart block who are at increased risk for sudden death from cardiac arrest. If AV block is related to drug therapy, alternative drug regimens may be explored; however, in some patients, permanent pacing and continuation of drugs (despite AV block) may constitute the best medical management.

## 10.3 Description of Procedure

Permanent pacemakers consist of two parts: a pulse generator, and one or two long wire pacing electrodes. The pulse generator contains a power supply and electronic devices to sense the patient's own heart beats and to supply artificial or "paced" beats when necessary. The pulse generator is implanted in the chest wall. In nearly all cases, the electrodes are passed transvenously under fluoroscopic guidance from the pulse generator to the interior of the heart, where they become embedded in the wall of the heart. The procedure is usually performed under local anesthesia, most often in inpatient settings to allow for adequate observation of the patient and monitoring of pacemaker function.

Bleeding and local discomfort are the most common complications. Infection occurs rarely. Other uncommon complications are deep venous thrombosis, pulmonary embolism, displacement or fracture of the electrodes, and premature failure of the pulse generator. Patients require routine follow-up to ensure proper pacemaker function, especially near the end of the battery's expected life. Power supplies, pulse generators, and pacemaker wires can be replaced if necessary.

## 10.4 Changes in Technology

The first fully implantable cardiac pacemaker was developed in 1959. Permanent cardiac pacemaker technology has advanced rapidly over the past 30 years. Pacemakers are now smaller, lighter, and have longer-lasting power supplies (5 to 10 years). They can also be reprogrammed after implantation, using externally applied magnets or radio waves, so that the function of a single implanted pacemaker may change as the nature of the patient's cardiac disease changes. Many newer pacemakers can transmit information via telephone to a physician's office, allowing for easier monitoring of pacemaker function.

The first pacemakers were relatively simple devices which discharged at a constant rate to stimulate ventricular contraction. Now, all artificial pacemakers perform two functions: first, to sense the heart's own spontaneous

electrical discharges, and second, to initiate artificially paced beats as necessary. Pacemakers which sense the heart's spontaneous beats and respond appropriately are called demand pacemakers. All modern pacemakers are of this type.

Artificial pacemakers also have several possible "modes of response." In the commonly used ***inhibited*** mode, a spontaneous electrical discharge originating in the heart will, if sensed properly by the pacemaker, inhibit the pacemaker from discharging for a very brief interval. As long the heart's intrinsic pacemaker is functioning adequately, the artificial pacemaker will not discharge. Pacemakers can also be reprogrammed to operate in ***triggered*** or ***asynchronous*** modes. These modes are used primarily to adjust the sensitivity and output of pacemakers.

Older pacemakers were designed to sense spontaneous discharges only in the ventricles and to provide artificially paced beats only to the ventricles. Pacemakers of this type are referred to as single-chamber or VVI (for ventricular-paced, ventricular-sensed, inhibited). Although they certainly saved many lives, VVI pacemakers were also associated with some side effects. When only the ventricles are paced, atrial contraction may occur but will not be synchronized properly with ventricular contraction. For some patients, the loss of atrial contribution to ventricular filling results in decreased exercise tolerance. Other patients experience a drop in blood pressure, dizziness, or syncope when an implanted VVI is artificially pacing the heart; these patients are said to have a "pacemaker syndrome."

Around 1985, pacemakers became available which could sense spontaneous discharges in the atria as well as in the ventricles, and could also provide electrical discharges to both the atria and ventricles. They can operate in both inhibited and triggered modes. These pacemakers are called dual-chamber, AV-sequential, or DDD devices (for dual-sensed, dual-paced, dual mode). DDD pacemakers can provide physiologic sequential pacing of the atria and ventricles, improving exercise tolerance in some patients. They also eliminate the pacemaker syndrome. However, they are substantially more

expensive, more difficult to implant (since both atrial and ventricular leads must be positioned correctly), and require more time for programming and follow-up than VVI pacemakers.

VVI and DDD pacemakers are the two types of pacemakers most commonly used today. DDD pacemakers do offer clinical advantages in some patients. However, for most patients, the difference between VVI and DDD devices is a marginal one. While DDDs account for an increasing share of initial pacemaker implants, their advantages are not sufficient to warrant large-scale replacement of older VVI implants with DDDs. Furthermore, although DDDs may improve exercise tolerance in some patients, they do not expand the clinical applications in which pacemakers are used: both VVIs and DDDs are used primarily in patients with bradycardia from SA or AV node dysfunction. For these reasons, the introduction of DDD pacemakers is unlikely to be responsible for a significant increase in pacemaker implantation.

## 10.5 Changes in Indications for Pacemaker Implantation

In the 1960s, most pacemakers were being inserted for AV block. By 1989, the most common indication for pacemaker insertion was SA node dysfunction. In either case, pacemakers were inserted to prevent symptoms from bradycardia and pauses, and prevention of such symptoms remains the primary purpose of pacemakers. However, the rate of pacemaker implantation for bradycardia is likely to increase in Medicare beneficiaries for two reasons. First, the incidence of conduction disorders is growing along with the "old old" segment of the population. Cardiologists are likely to have become more aggressive in treating bradycardia with pacemakers in these patients because of the low morbidity and excellent outcomes expected with the procedure. Second, the use of drugs affecting AV node conduction is growing, and has undoubtedly increased the number of patients in whom permanent pacing is indicated, especially in the very old.

In the 1980s pacemaker technology was applied to the treatment of tachycardia as well as bradycardia. Rapid, precisely-timed artificially paced beats can often interrupt an abnormal rapid heart rhythm, if the pacemaker is sophisticated enough to detect the rapid arrhythmia and to respond with appropriately timed discharges. Pacemakers have also been designed which incorporate cardioverters and defibrillators, devices which deliver larger electrical shocks to the heart to terminate more erratic arrhythmias. However, in the period 1985 to 1989, pacemakers incorporating these technologies were still considered experimental by the FDA, and would not account for any increase in pacemaker insertion under Medicare.

A separate technology which deserves mention is the ***automatic implantable cardiac defibrillator*** (AICD). These devices also are designed to terminate erratic and life-threatening cardiac arrhythmias, and have been in clinical use since the mid-1980s. However, unlike pacemakers, AICDs are not designed to treat bradycardia by sensing and pacing the atria and/or ventricles. AICDs represent a separate and distinct technology and are never billed as pacemaker insertions; specific codes for billing AICD implantation first appeared in the 1987 edition of the AMA's Physicians' Current Procedural Terminology (CPT), published in November 1986.

## 10.6 Shifts of Procedures to Ambulatory Settings

Permanent pacemaker implantation is nearly always performed in inpatient settings because of the need for intensive monitoring and adjustment of the pacemaker following implantation. Little shift of primary implantations to ambulatory settings is expected to have occurred between 1985 and 1989. However, battery replacement (a procedure not included in this study) is routinely performed in ambulatory settings.

## 10.7 Development of Clinical Guidelines for Pacemaker Implantation

In 1984 the American College of Cardiology and the American Heart Association jointly published a set of guidelines for permanent cardiac

pacemaker implantation. In these guidelines, indications for pacemaker implantation were labeled as:

- Class I: Conditions for which there is general agreement that permanent pacemakers should be implanted;
- Class II: Conditions for which permanent pacemakers are frequently used but there is divergence of opinion with respect to the necessity of their insertion; or
- Class III: Conditions for which there is general agreement that pacemakers are unnecessary.

The guidelines discussed pacemaker indications with a great deal of clinical detail and specificity, and might have had some effect on utilization by themselves. However, their influence on practice was undoubtedly magnified by HCFA's directive to Peer Review Organizations in January 1986 regarding permanent pacemaker implantation. The directive mandated PRO review of <u>every case</u> of permanent pacemaker insertion to determine if the procedure was "reasonable and necessary", based on clinical information in the hospital admission record. Pacemaker implantations which did not meet PRO standards resulted in denial of reimbursement to the physician, and even denial of the hospital admission if pacemaker insertion was the sole reason for admission. PRO enforcement of clinical guidelines by withholding reimbursement likely had a significant impact on pacemaker insertion in patients with marginal indications (for example, patients who were not clearly symptomatic from their bradycardia).

## 10.8 Summary

Although pacemaker technology has evolved significantly over the past 30 years, improvements prior to 1990 did not significantly expand the application of pacemakers to a wider pool of patient. However, demand for pacemaker utilization under Medicare between 1985 and 1989 was undoubtedly influenced by increasing use of drugs affecting cardiac conduction, and by the growing numbers of very old in the population. PRO enforcement of clinical guidelines for pacemaker insertion, beginning in 1986, is likely to have moderated increases in utilization by discouraging the procedure in marginal cases.

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# 11.0 TRANSURETHRAL (TURP) AND SUPRAPUBIC PROSTATECTOMY (SP)

## 11.1 Relevant Anatomy and Pathology

The prostate is shaped like an inverted pyramid and is located directly below the bladder. It contains both muscle fibers and glandular tissue. The glandular secretions of the prostate constitute most of the volume of semen. Contraction of the muscle fibers causes emptying of glandular secretions during ejaculation. Anatomically, five rather indistinct ***lobes*** of the prostate have been described: ***anterior, median, posterior,*** and two ***lateral*** lobes. Functionally, the prostate consists of two concentric layers, derived from different embryonic tissues: the ***inner zone*** and ***peripheral zone*** both contain prostatic glands, but are separated by a distinct layer of muscle. The entire prostate is surrounded by a fibrous ***capsule***. The urethra, as it travels from the bladder to the penis, passes through the center of the prostate for about an inch; this section is called the ***prostatic urethra***.

One of the most common conditions affecting the prostate is ***benign prostatic hypertrophy (BPH)***, an abnormal but non-cancerous enlargement of the prostate. A normal prostate is about the size of a walnut; with BPH, it can double in size. The condition occurs primarily in men over age 45. In autopsy studies, more than half of men over age 50, and 90 percent of men over age 70, have evidence of BPH. It is associated with increasing age and normal levels of male hormones, but other etiologic factors are unknown. In BPH, it is the inner zone of the prostate that ***hypertrophies*** (grows abnormally large). Most of the symptoms of BPH are attributable to compression of the prostatic urethra, causing difficulty and delay in emptying the bladder ***(bladder outlet obstruction)***. The bladder often does not empty completely, and the resulting stagnant urine may lead to recurrent bladder infection. With chronic obstruction, the bladder must contract more forcefully to empty itself. As a result, the muscular wall of the bladder thickens (hypertrophies) and becomes overly sensitive (hyper-reflexic). The hypertrophied, hyper-reflexic bladder then gives rise to irritative symptoms: sudden and frequent urges to urinate, especially at night. Fragile, dilated

veins within the enlarged prostate can bleed intermittently, causing visible or invisible blood in the urine ***(gross or microscopic hematuria)***. As obstruction grows more severe, the increase in urinary pressure causes progressive enlargement of the bladder, ureters, and kidneys, with gradual loss of kidney function. Thus, BPH is not merely an inconvenience: if left untreated, it will eventually cause renal failure in a minority of patients.

## 11.2 Indications for Prostatectomy

Many men tolerate mild to moderate symptoms of prostatic obstruction for years. Symptoms may wax and wane over time, especially with changes in medications prescribed for other conditions (decongestants, anti-anxiety agents, some anti-arrhythmics, and other drugs). In fact, within the past few years many urologists have begun using a few of these medications to manage the symptoms of BPH.

For patients with severe obstruction of the urinary tract, the only effective treatment of BPH is the surgical removal of prostatic tissue, eliminating compression of the prostatic urethra. Such surgery will prevent or halt physiologic consequences of obstruction, such as hypertrophy of the bladder and deterioration of kidney function. However, the majority of prostatectomies are performed electively in patients who have moderate obstructive and irritative symptoms (frequent urination, difficulty voiding, and so forth), but who are not at immediate risk for renal damage.

## 11.3 Description of Prostatectomy

Several different surgical techniques have been developed for prostatectomy. These can be classified by the anatomical approach (transurethral, suprapubic, retropubic, and perineal*), or by the extent of surgery (simple or radical). In a radical prostatectomy, the entire prostate (including the capsule) is removed, along with the seminal vesicles and surrounding tissue. Radical prostatectomies are performed only in patients with prostatic cancer. In a simple prostatectomy, only the glandular tissue

is removed, leaving the prostatic capsule and surrounding tissues intact. Only the two most common types of simple prostatectomy, transurethral and suprapubic, will be discussed here.

## 11.4 Transurethral Prostatectomy (TURP)

Transurethral prostatectomy is the most common surgical technique, accounting for more than 90 percent of prostatectomies in the United States. Basically, a TURP involves the endoscopic cutting and removal of prostatic tissue, using the urethra as the endoscopic route to the prostate. Because this endoscopic surgery requires special training, all TURPS are performed by urologists.

The endoscope used in this procedure is called a ***resectoscope***, a thin rigid tube which contains three components: optical elements for viewing the prostate, channels for the passage of fluids, and a wire probe which ends in a loop. An electric current is passed through the loop, which is used to "cut" prostatic tissue. Small, repeated semi-circular passes are made with the loop, concentrically enlarging the intraprostatic urethral channel by chipping away at peri-urethral tissue (the inner zone of the prostate), and continuing until as much glandular tissue as possible has been removed. (The process may be likened to removing the flesh of an orange with a tiny spoon, until only the intact skin is left.) In order to maintain visibility, prostatic tissue and blood are removed by continuous or intermittent irrigation of the prostate with fluid through the resectoscope. The procedure may last from 30 to 90 minutes, depending on the size of the prostate and the amount of bleeding that occurs.

Spinal anesthesia is used in about 90 percent of cases, and general anesthesia in the remaining 10 percent. (Patient preference is the usual reason for using general anesthesia.) When the procedure is finished, a catheter is inserted into the bladder to drain urine (both anesthesia and obstruction-related stretching may decrease muscle tone of the bladder) and to

flush out blood (which may otherwise form clots and obstruct urine flow). The catheter is removed when the urine is clear of blood, usually within 24 to 72 hours. The average length of stay for TURP patients is four to five days.

## 11.5 Suprapubic Prostatectomy

This is an older surgical technique which has greatly decreased in popularity during the past two decades. Unlike TURP, suprapubic prostatectomy is not an endoscopic procedure. Currently, it is usually reserved for patients with very large prostates which would be difficult to remove endoscopically. Since it does not require special endoscopic training, non-urologists may perform suprapubic prostatectomies; in practice, however, nearly all are performed by urologists.

In the suprapubic approach, the lower abdominal wall is incised, revealing the bladder. The bladder is opened, and the floor of the bladder is then cut to expose the prostate lying beneath the bladder. Using a finger, the surgeon can easily separate and remove the glandular portion of the prostate from the fibrous prostatic capsule. Removal of the prostate gland is usually more rapid and more complete using the suprapubic approach.

Surgical incisions in the floor and the anterior wall of the bladder and in the abdominal wall are then closed with sutures. Eventually, the distended fibrous capsule will shrink and will be relined by urethral tissue.

As with TURP, about 90 percent of suprapubic prostatectomies are performed under spinal anesthesia, and the remainder under general anesthesia. Following the procedure, a urethral catheter is inserted to drain urine until the bladder regains muscle tone, and a suprapubic catheter is usually inserted into the bladder through the abdominal wall to flush blood from the bladder. Because the procedure involves open rather than endoscopic surgery, the average length of stay is much longer for suprapubic prostatectomy (9.4 days, vs. 4-5 days for TURP). The longer post-operative recovery period and the discomfort from abdominal surgical wounds undoubtedly account in part for the decline in popularity of this form of prostatectomy.

## 11.6 Complications

Minor complications which may occur with both forms of prostatectomy include post-operative bleeding, urinary tract infection, obstruction of the urethra by blood clots, and failure to void normally because of poor bladder tone. Treatment of these complications is usually routine.

Post-operative ***urethral stricture*** (narrowing) is a late complication of prostatic surgery, developing up to six months after surgery. In TURP patients, it is undoubtedly related to mechanical forces generated within the urethra by the resectoscope. It also occurs following suprapubic prostatectomy, perhaps because of the longer post-operative use of a urethral catheter. The incidence of this complication depends on how it is defined and diagnosed; clinically detectable narrowing of the urethra may occur in perhaps 20 percent of patients, but symptomatic strictures requiring urethral dilation occur in a far smaller number of cases. In a study of Manitoba data, Roos and Ramsey estimated the incidence of significant stricture as 4 percent following TURP, and 7 percent following suprapubic prostatectomy.

A related complication is ***bladder neck contracture***. The bladder neck is a circular band of muscle fibers at the point where the urethra joins the bladder. During a TURP, muscle fibers of the bladder neck are frequently cut in an attempt to remove as much glandular tissue as possible. Following surgery, the cut muscle fibers may form a circular scar, which contracts as it heals, narrowing the bladder outlet.

Regardless of the surgical approach, nearly all patients experience ***retrograde ejaculation*** postoperatively. Because of anatomical changes in the prostate, semen is ejaculated into the bladder and is later voided with urine. Such men are sterile, but this is usually not of concern in the age group at risk for prostatectomy. Impotence is another significant complication of prostatectomy. It may occur with any surgical approach. It is difficult to obtain accurate data on the incidence of impotence following prostatectomy; published estimates have ranged from 4 to 40 percent, but are probably closer to 5 percent. Erectile potency depends on the complex interaction of nerves, arteries, veins, and muscles, as well as psychological

and hormonal factors. Nerves and blood vessels may be accidentally cut during open prostatectomy, or may be damaged by heat during TURP. Finally, many men experience anxiety or depression following genitourinary surgery. Evaluation of post-surgical impotence requires months of follow-up together with a combination of psychological counseling, invasive and non-invasive testing, and perhaps medical or surgical treatment.

A small percentage of men undergoing prostatectomy for BPH will require repeat prostatectomy. In Roos' study of Manitoba data, prostatectomy was repeated within two years for 4.5 percent of patients with TURPs, but only 0.8 percent with suprapubic prostatectomies. By eight years, the incidence of repeat prostatectomy exceeds 15 percent for TURP patients and 7 percent for patients with initial open prostatectomies. Since TURP entails the endoscopic removal of the prostate in small pieces, some prostatic tissue is inevitable left behind. Because this residual tissue remains under hormonal control, the process of benign prostatic hypertrophy continues and bladder outlet obstruction may recur, requiring repeat surgery in some cases. In suprapubic prostatectomy, removal of glandular tissue is more likely to be complete, and BPH is less likely to recur.

Finally, peri-operative death must be discussed as a complication of prostatectomy. Patients undergoing prostatectomy are nearly exclusively older men and have a high prevalence of heart disease. Peri-operative deaths are therefore often related to cardiovascular events, precipitated by side-effects of anesthesia, the stress of surgery, or the effects of fluid administration during surgery. The latter is particularly important during TURP procedures. When extensive amounts of prostatic tissue are removed transurethrally, large veins in the peripheral prostate may be cut and exposed. Substantial amounts of irrigation fluid can be absorbed rapidly through these veins. If large enough, such fluid absorption can cause a variety of symptoms and signs (referred to collectively as the "TURP syndrome") such as nausea, vomiting, visual disturbance, slowing of the heart rate, hypertension or hypotension, delayed recovery from anesthesia, mental confusion, coma, and even death. Fortunately, although some amount of irrigation fluid is absorbed in all TURPs, the TURP syndrome occurs in less than 1 percent of cases. Its risk can

be minimized by reducing the pressure of the irrigating solution, avoiding lengthy surgical sessions, and terminating the procedure when large veins are exposed. (The syndrome does not occur in suprapubic procedures because the amount of irrigating fluid is insignificant.)

Mortality rates within 90 days of surgery appear to be comparable between TURP and suprapubic prostatectomies. Mortality is higher in older patients, in patients with pre-existing renal impairment, and when surgery is performed in small hospitals (< 150 beds).

## 11.7 Changes in Technology Affecting Risk/Benefit Ratio

Technologically, the procedures for both TURP and suprapubic prostatectomy have been relatively stable over the past decade. There have been minor improvements in the optical components of resectoscopes, allowing a wider field of vision. However, no procedure-related technological changes have occurred which would significantly alter the risk/benefit ratios associated with these two forms of prostatectomy.

A few surgical treatments have been developed as alternatives to prostatectomy. These include balloon dilation of the intraprostatic urethra, and placement of intra-urethral stents (small springlike devices which uncoil after insertion to maintain urethral patency). However, enthusiasm for balloon dilation is already waning, while stent placement has not been sufficiently tested to allow assessment of its value. Other untested technologies include laser ablation of the prostate, and intra-urethral use of hyperthermia to cause gradual sloughing of prostatic tissue.

Within the past few years, however, a medical innovation has appeared as a competing technology, and has markedly reduced the number of patients seeking surgery purely for relief of symptoms (rather than for treatment of severe obstruction). As mentioned above, some medications have the side effect of reducing muscle tone in the bladder and prostate. Two such agents (prazocin and terazocin) are approved by the FDA for the treatment of hypertension, but have been used successfully by many urologists to treat the symptoms of BPH. Since most of the symptoms of BPH occur from prostatic compression of the urethra, and from increased muscle tone and spasm in the

hypertrophied bladder wall, medications which reduce muscle tone even slightly may sufficiently alleviate symptoms so that surgery can be avoided. In this respect, medical treatment can be seen as increasing the relative risk/benefit ratio of prostatectomy, since similar benefits can be achieved without the risks of surgery. Terazocin has the advantage of requiring only once-a-day dosage, and has proved to be popular with patients. Since such medical therapy is new, it is unknown how long patients may expect to obtain symptomatic relief from such medications. Since BPH is a progressive disease, it is likely that many who opt for medical therapy will ultimately require surgical treatment. In the meantime, however, these medications (particularly terazocin) have significantly reduced utilization of prostatectomy.

## 11.8 Changes in Indications for Prostatectomy

The indications for simple prostatectomy are relatively circumscribed: it is used only for the treatment of BPH. These indications have not changed. However, there may be a trend among urologists to perform prostectomy earlier in the course of BPH, before permanent anatomic changes related to bladder outlet obstruction (such as thickening of the bladder wall) can occur.

## 11.9 Shifts of Procedures to Ambulatory Settings

A few urologists have performed TURPS in day-surgery settings. However, the results have been unpopular with both patients and physicians. Without frequent nursing care, urinary catheters are likely to become blocked by blood clots, resulting in painfully distended bladders, urgent calls to urologists, and visits to emergency rooms.

Suprapubic prostatectomies are not performed in ambulatory settings because of the use of low abdominal incisions.

## 11.10 Development of Clinical Guidelines for Prostatectomy

In January 1988, the American Urological Association (AUA) adopted a policy statement regarding TURP. The statement recognized each of the following conditions as a valid indication for TURP:

- urinary retention due to prostatic obstruction;
- intractable symptoms due to prostatic obstruction;
- recurrent or persistent urinary tract infection related to prostatic obstruction;
- recurrent gross hematuria caused by prostatic enlargement.

In addition, acceptable indications for TURP exist in patients with two or more of the following conditions:

- documented post-voiding residual urine [incomplete emptying of bladder];
- pathophysiologic changes of the kidneys, ureters or bladder caused by prostatic obstruction;
- abnormally low urinary flow rate;
- normal flow rate but with abnormally high intravesical [within the bladder] voiding pressure secondary to prostatic bladder obstruction.

These guidelines reflected the existing "common sense" standards of practicing urologists, and are unlikely to have had any effect on utilization of TURPs.

The AUA expects to release its first comprehensive policy statement regarding the treatment of BPH by the end of 1991. This guideline will discuss all surgical approaches, including suprapubic prostatectomy.

## 11.11 Summary

Both TURP and suprapubic prostatectomy are technologically stable procedures with unchanging indications. Neither procedure is performed routinely in ambulatory settings, and guidelines released in 1988 are unlikely

to have affected utilization. However, the introduction within the past few years of medical therapy to reduce the symptoms of BPH is likely to cause a dramatic decrease in the number of prostatectomies performed, at least in the short run. It is possible that the popularity of medical therapy may decline with greater experience, and it is very likely that medical therapy merely postpones surgery for the majority of men with BPH.

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*Transurethral prostatectomy is an endoscopic procedure; the other three are referred to as"open" prostatectomies.

# 12.0 UPPER GI ENDOSCOPY

## 12.1 Relevant Anatomy and Pathology

The upper GI tract includes the ***esophagus***, the ***stomach***, and the ***duodenum*** (the first segment of the small intestine). The esophagus is a muscular tube which propels food from the throat to the stomach. The process of digestion, which begins when salivary enzymes are mixed with food during chewing, is continued in the stomach by mechanical mixing and the addition of gastric enzymes (pepsin), and in the duodenum by pancreatic enzymes (amylase, lipase, and protease). All three organs contain a muscular layer, and an inner lining of mucous-secreting tissue called a mucous membrane. Most common disorders of the GI tract arise in mucous membranes.

Common diseases of the esophagus include:

- inflammation due to gastric or intestinal contents flowing back into the esophagus;
- infections, primarily from viruses and yeasts in immunosuppressed patients;
- swallowing disorders from damage to esophageal muscle or nerves;
- bleeding disorders, related commonly to tears in esophageal tissue after vomiting, or to ***varices***, which are abnormally enlarged hemorrhoid-like veins seen usually in alcoholic liver disease;
- primary cancer of the esophagus.

Common disorders in the stomach and duodenum include inflammation and peptic ulcer disease. ***Gastritis*** (inflammation of the stomach) may be caused by medications, alcohol, or stress associated with severe illness or injury. ***Peptic ulcers*** (deep erosions of the mucous membrane) occur in both the duodenum and the stomach. Various factors, including increased acid secretion, the presence of certain bacteria, and certain medications, increase the risk of peptic ulcer. Peptic ulcers occurring in the stomach must be distinguished from ***primary gastric carcinoma***, which can also have an ulcerated appearance on X-ray or endoscopy. However, since primary cancer of the

duodenum occurs very infrequently, ulcers occurring in the duodenum are always considered to be benign. All three of these conditions (gastritis, peptic ulcers, and gastric carcinoma) can be the cause of upper GI bleeding.

## 12.2 Description of Procedure

Upper gastrointestinal (UGI) endoscopy is used to visually examine the tissues lining the upper gastrointestinal tract. Frequently, the procedure is referred to by a more specific name which indicates the portion of the GI tract examined: e.g., ***esophagoscopy*** (esophagus alone), or ***esophagogastroduodenoscopy*** (esophagus, stomach, and duodenum).

The endoscope is a long tube containing flexible glass fibers (fiberoptics) which transmit light. One end of the endoscope is passed through the mouth and throat to the area to be examined (esophagus, stomach, or duodenum). The other end of the scope is connected to a light source. The light travels down the glass fibers to the tissue being examined, and an image of the illuminated area is transmitted back up the fibers to the viewing head, which is an eyepiece similar to that on a telescope. The endoscopist performing the procedure has a small circular field of vision, the contents of which change rapidly as the scope is advanced, withdrawn, or moved laterally within the GI tract. The tip of the endoscope can be flexed in any direction to help negotiate turns and to look at lesions head-on. In addition to fiberoptics, the endoscopic tube contains channels for suctioning of blood and other fluids, and for obtaining tissue samples by means of brushes or biopsy forceps.

UGI endoscopy is usually performed with both local anesthesia (to eliminate the sensations of touch and pain in the throat) and with intravenous sedation (to alleviate anxiety and restlessness during the procedure). The patient is conscious throughout the procedure, which lasts about 15 to 30 minutes. At least one assistant (typically a nurse) is usually present. Patients must prepare for the procedure by fasting overnight. Although the endoscope may create local discomfort and even gagging when passed through the throat, complications of the procedure are very infrequent. Major

complications include bleeding and perforation. Some patients may become oversedated from intravenous medication, with transient respiratory depression. Rarely, patients experience a significant drop in heart rate and blood pressure as a result of reflexes stimulated by the endoscope. These complications, although very rare, can be fatal; therefore, UGI endoscopy is usually performed in ambulatory settings within hospitals (endoscopy suites), instead of in physicians' offices, so that adequate support services are available for those patients who do experience respiratory or cardiovascular complications. Since the late 1980s, monitoring of blood pressure, blood oxygen levels, and heart rhythm has become common during UGI endoscopy, so that respiratory and cardiovascular problems can be detected as quickly as possible.

## 12.3 Indications for Upper GI Endoscopy

The most frequent use for UGI endoscopy is in the evaluation of ***dyspepsia***. Dyspepsia refers to a vague complex of symptoms that includes pain or discomfort in the upper abdomen, accompanied by burning, bloating, belching, nausea, and/or other symptoms. The differential diagnosis in patients with these symptoms includes gastric ulcer, duodenal ulcer, and gastric cancer. When none of these more serious conditions is found, the symptom complex described above is labelled "dyspepsia." UGI endoscopy is used in the evaluation of dyspepsia to rule out more serious disease by visual inspection of the lower esophagus, stomach, and duodenum, with biopsy of any lesions that may be malignant. (An "upper GI series" of X-rays can also be used to detect ulcers and gastric cancer, but is a less sensitive and less specific test.)

Most gastroenterologists do not endoscope patients at the first appearance of dyspepsia, but will rather begin a course of antacids or other medications. Even symptoms caused by ulcers are usually relieved within a week of beginning such medical therapy. Endoscopy for dyspepsia is usually reserved for patients with unrelenting or recurring symptoms, or patients who

appear to be severely ill. In these instances, the possibility of gastric cancer looms higher, and visualization and biopsy by endoscopy becomes more important.

Endoscopy is also used in the evaluation and treatment of upper GI bleeding. The most frequent causes of bleeding are ulcers, gastritis, varices, and small tears in the esophagus which may occur after vomiting. In cases of active bleeding, UGI endoscopy offers an advantage over X-ray studies: not only can the precise source of bleeding frequently be visualized, but control of bleeding can often be achieved through endoscopic techniques such as cauterization (closing off bleeding vessels with heat or electric current).

UGI endoscopy is nearly always indicated in the evaluation of esophagitis, esophageal masses, swallowing disorders, and other esophageal disease, both for diagnosis (visualization and biopsy) and therapy (dilation of narrowed areas, debulking of tumors).

## 12.4 Changes in Technology Affecting Risk/Benefit Ratio

In the mid- to late-1980s, several improvements in endoscopic technology made the procedure more tolerable for patients. First, endoscopes with smaller diameters became available, making the procedure more comfortable for patients. Although the use of local anesthetics reduces or eliminates the sensations of touch and pain in the throat, patients are still able to feel pressure when a larger-diameter endoscope pressed against the back of the throat. Smaller endoscopes are also easier to maneuver from the stomach into the narrower duodenum.

A second change that may have affected the risk/benefit ration is the use of video technology. Video endoscopes have been available since about 1984; a second generation of videoscopes with improved quality became available around 1988. With a videoscope, the area under examination is displayed on a video screen instead of through an eyepiece. The image is larger and can be viewed by several observers at the same time; it can also be videotaped. The greatest advantage of videoscopes is the ability to document

and communicate endoscopic findings more completely and accurately: clinical teaching is more effective, and videotaped procedures can be replayed to review pathologic findings and endoscopic therapeutic maneuvers. For these reasons, videoscopes have become essential in teaching hospitals, and may well have resulted in improved quality of endoscopic diagnosis and treatment in such facilities. However, the high cost of videoscopes (about ten times that of standard scopes) has limited their diffusion in non-teaching settings.

Third, changes in anesthesia have altered the risk/benefit ratio somewhat. In 1986 a new intravenous sedative became available which increased patient tolerance of the procedure. The new drug, Versed, is similar to Valium and can be used intravenously with a rapid onset of action. It can be used alone or with a narcotic such as Demerol to sedate patients and reduce anxiety during brief procedures such as endoscopy. However, it has a shorter half-life than Valium. Patients recover more rapidly from its effects and can be discharged from ambulatory surgical facilities more quickly and without lingering sedation. Versed has the additional advantage of causing amnesia for the procedure in the majority of patients: although they remain conscious during the endoscopy, they later do not recall the procedure or any associated discomfort.

Finally, improvements in technology have expanded the therapeutic benefits of upper GI endoscopy. Active bleeding in the upper GI tract (usually from ulcers or esophageal varices) can be controlled by electrical cauterization or coagulation with a heat probe or laser. Esophageal varices (those hemorrhoid-like veins that are prone to bleeding) can be treated endoscopically by injecting them with chemical agents which cause inflammation and eventual fibrosis of the vein; this process is called ***sclerotherapy*** and has been available since about 1980. In a newer endoscopic treatment for varices, available only since about 1988, rubber bands are placed around the base of the varices, eliminating their blood supply. This procedure ***(ligation of varices)*** may be just as effective and have fewer complications than sclerotherapy: the needles used in sclerotherapy can sometimes puncture the esophageal wall, with injection of highly irritating chemicals into the midline structures of the chest.

Therapeutic upper GI endoscopy is also used in the palliative treatment (affording relief, but not cure) of esophageal cancer, either by debulking the tumor with a laser or by placing a stiff tube through the narrowed cancerous area, to allow passage of soft foods and liquids.

In patients who are unable to swallow because of debilitating conditions such as stroke or Parkinson's disease, feeding may be accomplished through a gastrostomy tube placed into the stomach through the abdominal wall. Until the early 1980s, initial gastrostomy tube placement was performed under general anesthesia. A technique has been developed, however, in which these tubes can be inserted using an endoscope and local anesthesia. Endoscopic placement of gastrostomy tubes has now become routine, and can be performed in five to ten minutes, eliminating the risk of general anesthesia.

## 12.5 Changes in Indications for Upper GI Endoscopy

The principal uses of diagnostic endoscopy are the evaluation of dyspepsia; examination of mucosal membrane lesions of the esophagus, stomach, and duodenum; investigation of active bleeding in these areas; and assessment of abnormal narrowing or dilation of the esophagus caused by nervous or muscular disorders. These indications have not changed since the introduction of the procedure.

As discussed above, the role of upper GI endoscopy as a therapeutic procedure has expanded greatly. However, therapeutic procedures (whether for control of bleeding, treatment of esophageal narrowing, or placement of gastrostomy tubes) account for a small proportion of upper GI endoscopy; most upper endoscopy is performed for diagnostic purposes.

## 12.6 Shift to Ambulatory Settings

Upper GI endoscopy has been considered an ambulatory procedure for many years, and no patient is admitted simply for endoscopy. However, patients may be endoscoped in inpatient settings when admission is required for medical or

surgical reasons (for example, active GI bleeding; severe dehydration and/or malnutrition, perhaps from GI disease; related or unrelated major surgical procedure).

Although upper GI endoscopy has long been an ambulatory procedure, it has remained by and large hospital-based: it is usually performed in endoscopy suites located physically within a hospital, so that support staff are available if complications occur. (When necessary, the procedure may also be performed in an intensive care unit or emergency room.) There are instances, however, in which groups of gastroenterologists have set up office-based endoscopy suites, free-standing facilities in which adequate support staff are available if needed. Third-party reimbursement regulations may discourage office-based procedures, however, if no facility charge is allowed to compensate for the overhead of maintaining stand-by support services.

## 12.7 Development of Clinical Guidelines for Upper GI Endoscopy

In 1985, the Health and Public Policy Committee of the American College of Physicians (ACP) published a position paper on the role of upper GI endoscopy in the evaluation of dyspepsia. Citing statistics that only 20 percent of patients with dyspepsia have ulcers and less than one percent have gastric cancer, the guidelines recommended that endoscopy not be performed in the initial evaluation of dyspepsia, but be reserved for those patients who:

- have symptoms despite 6 to 8 weeks of appropriate anti-ulcer medical therapy (cessation of alcohol, tobacco, and ulcerogenic medications such as aspirin; institution of anti-ulcer medications such as antacids or histamine blockers);
- have no response after 7 to 10 days of anti-ulcer therapy;
- have complications of ulcer disease (e.g., bleeding);
- show signs of severe systemic illness (e.g., significant weight loss); or
- have recurrence of symptoms during or following completion of therapy.

These guidelines reflected common beliefs regarding the use of endoscopy in 1985 when they were published, and so they are unlikely to have had much impact on utilization. However, dyspepsia is a relatively common symptom complex, and inappropriate endoscopic evaluation of dyspeptic symptoms represents an area in which significant overutilization of endoscopy may be occurring. Brook et al., using 1981 medical records data for 1058 Medicare patients who had undergone upper GI endoscopy in five states, found that 17 percent of these endoscopies represented inappropriate overuse, and that the use of the procedure was equivocal in another 11 percent of cases. Endoscopies were more likely to be appropriate if performed in a teaching hospital, but less likely to be appropriate if performed by a board-certified gastroenterologist. No estimates of overutilization during the late 1980s are available. However, the impact of the ACP's guidelines on overutilization may have been limited since they were not enforced by medical professional organizations or by third-party payors.

In 1988 the American Society for Gastrointestinal Endoscopy (ASGE) published a number of guidelines related to upper GI endoscopy, covering such issues as the role of endoscopy in the management of upper GI bleeding, and the role of endoscopy in the management of peptic ulcer disease. All of these guidelines were brief (1 or 2 pages), and again reflected common practice.

Many medical journals carry advertisements for short training courses in endoscopic procedures. These courses typically last a few days to a week, and involve classroom instruction and the use of artificial models, rather than actual supervised experience with patients. Guidelines published by the ACP in 1987 and the ASGE in 1988 indicate that such courses do not provide sufficient preparation to perform upper GI endoscopy, and that hospitals should not grant privileges to physicians whose endoscopic training is limited to these courses. The 1987 ACP training guidelines require a minimum of 50 supervised procedures (with patients, not artificial models) for certification of clinical competence.

The concern addressed by these training guidelines is that physicians with inadequate training may be purchasing endoscopes and performing these procedures. However, the impact of these guidelines on the quality of

training is uncertain. Supervised endoscopic experience has been part of gastroenterology training programs for at least a decade, and nearly all recent graduates of such programs would meet or exceed published guidelines for clinical competence in endoscopy. Many older gastroenterologists have completed approved endoscopic training courses to gain clinical competence. Since most upper GI endoscopy has been performed in hospital endoscopy suites rather than in physicians' offices, hospital restrictions on privileges would reduce the possibility of poorly qualified physicians performing endoscopy. It is likely that a few physicians (particularly surgeons, who are procedure-oriented and have access to operating rooms) have begun performing upper GI endoscopy without completion of approved training. However, even with the availability of short (and inadequate) endoscopic training courses, it is extremely unlikely that increased utilization of upper GI endoscopy is attributable to diffusion of the procedure to a large number of medical and surgical generalists.

## 12.8 Summary

Upper GI endoscopy is a useful tool in the diagnosis and therapy of a variety of disorders of the esophagus, stomach, and duodenum. The greatest technological changes in the late 1980s have been involved therapeutic uses of endoscopy to control bleeding, treat varices, dilate narrowed areas of the esophagus, and insert gastrostomy tubes. However, these therapeutic uses account for a small part of the utilization of upper GI endoscopy. Changes in overall utilization rates for the procedure would have been influenced heavily by the use of diagnostic endoscopy. Although the indications for diagnostic endoscopy have not changed, the number of gastroenterologists has grown substantially (by 22 percent between 1985 and 1989, according to AMA data), and a change in supply may perhaps have had the greatest influence on utilization. In addition, patients and referring physicians are more aware of endoscopy as a diagnostic tool; increased demand for a definitive diagnostic procedure (and fear of loss of referrals) may cause gastroenterologists to perform endoscopy earlier in the course of symptoms than suggested by clinical guidelines, thus contributing to growth in utilization rates for endoscopy.

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# APPENDIX A

# PARTICIPATING CONSULTANTS

# APPENDIX A

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